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ORAL HEALTH FOR CHILDREN WITH SPECIAL HEALTHCARE NEEDS (CSHCNs)

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CONTENTS

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ABSTRACT

Oral health is a very important aspect of general health, especially for vulnerable groups such as children with special healthcare needs (SHCNs). The oral care management of these children may require additional considerations, but evidence of the effectiveness of 'different' types of treatment in this population is limited. Pain-free treatment is important to reduce fear and anxiety in children. Different methods have been described for delivery of local anaesthetic with no agreement on which intervention is most successful in increasing its acceptance by children. In additional to professional considerations for oral care management, parents' views and understandings of oral care provision for their children is also of importance.

Aims: (i) To assess the quality of clinical guidelines and the underpinning evidence to support oral care recommendations for children with special healthcare needs; (ii) To assess the effect of interventions for increasing the acceptance of local anaesthesia for children with and without special healthcare needs who are receiving dental treatment; (iii) To assess parental perceptions of the provision of oral care that children with special healthcare receive; (iv) To identify potential evidence-based interventions to overcome some of the identified barriers of oral care delivery for children with special healthcare needs.

Methods: (i) Guidelines in paediatric dentistry published from 2007 onwards were appraised using the AGREE II instrument. The guidelines were qualitatively assessed to determine if there was a robust body of evidence to support their recommendations; (ii) A systematic review of RCTs, using the Cochrane methodology, was performed in order to determine the effect of methods for acceptance of local anaesthetic (LA) in children with and without special healthcare needs; (iii) A qualitative study, using semi-structured interviews and thematic analysis was undertaken to investigate parental views of the oral care provided for children with special healthcare needs; (iv) A systematic review of evidence aimed at overcoming barriers to the delivery of oral care, was undertaken.

Results: (i) The quality and reporting of guidelines for children with SHCNs in paediatric dentistry is very poor. The underpinning evidence that supports recommendations for children with SHCNs is also very limited. (ii) There is insufficient evidence to support any of the assessed interventions to increase the acceptance of LA due to variations in the reported methods, outcomes and timing of outcome measures. (iii) Several themes were identified:

importance of oral health, parental roles oral care experiences relating to dental appointments, existing issues with current oral care, and parental views of ideal practice. (iv) Five systematic reviews and five guidelines were identified assessing interventions aimed at improving the delivery of oral care for children with special healthcare needs. Potential interventions include fluoride application, training and education programmes aimed at both caregivers and the dental team.

Conclusions: The development and content of clinical guidelines focussing on oral care for children with SHCNs is concerning and the evidence base for their recommendations is limited. Guidelines in this area should be read with caution. The research and dental community need to work together to enhance the current standard of clinical guidelines in paediatric dentistry, specifically for children with special healthcare needs. High quality RCTs of interventions for increasing acceptance of local anaesthetic in children and adolescents having dental treatment are required including children with SHCNs as participants. These should be fully reported according to CONSORT standards. Studies should consider the development and use of core outcome measures to increase the opportunity for pooling of data. The findings of this thesis also point to the need for improvements to the entire network of dental care services to this population. Oral care providers should establish and maintain good communication with the parents of these children and help them in obtaining required support. A number of interventions are needed in order to increase the awareness of parents and caregivers regarding the treatment as well as prevention measures of dental diseases.

DECLARATION

No portion of the work referred to in the thesis has been submitted in support of an application for another degree or qualification of this or any other university or other institute of learning.

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I studied Dentistry as an undergraduate at King Saud University, Saudi Arabia during 2006-2011. During my undergraduate studies, I was impressed and motivated by community and public health dentistry. In 2013, I decided to pursue a master's degree in Public Health at The Johns Hopkins University, United States. After I got my master's degree in 2015, I came back to Saudi Arabia and I worked as a lecturer in the preventive department at Majmaah University for one year. In 2016, I was awarded a scholarship by the university to pursue a PhD degree; therefore, I applied to be a PhD student supervised by Prof. Walsh and Prof. Glenny from April 2017. This experience has been immensely beneficial to my research growth and knowledge base. I understand that I am in a very fortunate situation, and I am looking forward to seeing what the future holds when I conclude my PhD.

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CHAPTER ONE

1.1 Introduction

This opening chapter provides an introduction to the research, defines the research objectives and provides a summary of the topic. Moreover, the terms most commonly used in the course of the research are also explained, with the wider context of the study also discussed.

1.2 Background

Children with special healthcare needs (SHCNs) comprise an expansive section of society, encompassing children living with chronic physical, cognitive, communication and/or behavioural difficulties (1,2). More than 1 billion people (roughly 15% of the global population) are recorded as having some sort of disability or special need (3). Of these, there are an estimated 93 million children (aged 0-14) who are living with moderate or severe needs; of these, 13 million children suffer severe difficulties. For people aged 15 or over, around 892 million live with moderate or severe needs, with 175 million living with severe difficulties (3).

According to an estimate of the World Health Organization (WHO), the proportion of the population living with disabilities or special needs in developing countries amounts to 12%, while the same indicator in developed countries stands at 10% (4,5). Specifically, in the UK, there has been an increase in the number of children categorised as living with physical and developmental disabilities over the last fifteen years (6,7). As many as 800,000 children in the UK live with disabilities (6). This increase can, in part, be explained by various factors including the improved care of preterm infants and children recovering from trauma, as well as advances in the clinical treatment of long-term ailments (8).

In the UK, 6% of children are recorded as disabled or around one out of 20 children below the age of 16 are disabled (9,10). In Saudi Arabia, 6.3% of children have a disability or need of some type, one-third of which are physical (11). The rising number of the population living with disabilities

and special needs stem from many medical improvements through the years, as chronic conditions are now much better treated (6,12,13).

There is, however, a deficiency in the calculation of the estimates of the global data when it comes to the prevalence of individuals with special needs or disabilities, and it is thus a matter of urgency that a robust, comparable and comprehensive dataset is collected in this regard (14). It can be problematic to obtain accurate data on children living with special health needs given the spectrum of conditions that may be included in this term. The identification and categorization of SHCNs in the majority of developing nations are also hindered by shortcomings in culture- and language-specific instruments for data collection (4,5). Another factor obstructing developing nations in this area is the lack of proper registration, as well as the limited availability of culturally appropriate clinical and diagnostic services, which leads to inaccurately low numbers being reported (3). Given these restrictions, many children with SHCNs remain undiagnosed and thus are denied the healthcare they require. Due to the failure to detect and allocate adequate care, children with SHCNs remain disadvantaged (9).

Healthcare infrastructures are frequently under strain from the complex challenges presented by an ever-increasing population with SHCNs (15). Children with SHCNs tend to visit medical facilities on a more regular basis, and for longer periods, than their counterparts living without disabilities (16). The specific service demands in the UK have been outlined in the *National Service Framework for Children, Young People and Maternity Services* (17), and in government policies entitled *Valuing People* (18), and *Together from the Start* (19) (which emphasised the necessity of clear communication and the acknowledgement of how families are affected by caring for children with SHCNs.

1.3 Special healthcare needs (SHCNs)/Disability definition

There has been a range of definitions put forward for SHCNs and disabilities across the globe, but consensus on a standard classification has yet to be reached. The WHO classifies “disabilities” as a broad term that encompasses activity restrictions and impairments (12). A wide definition was

proposed by McPherson et al. (1998) and is listed on the official website of the American Academy of Paediatrics. It defines children with SHCNs as: “those who have or are at increased risk for a chronic physical, development, behavioural, or emotional condition and who also require health and related services of a type or amount beyond that required by children generally” (20).

Children are categorised as having a SHCN if they are living with a health condition that limits their ability to function in one or multiple aspects. These can include physical mobility, cognitive or sensory functions, memory, or self-control, among a variety of other aspects (21). To be more specific, “children with special needs” have been defined as “young people experiencing serious and persistent physical, psychological and/or social problems” (16,22). This definition has found acceptance among children with disabilities and their families (17). Accordingly, in this research, the aforementioned abbreviation SHCNs is applied to children living with chronic and permanent physical, psychological and/or social difficulties, to the extent that they are in need of specific services and/or attention not required by their ‘healthy’ peers (20,22,23).

The definitions applied to children with SHCNs differ from one country to the next and may change over time. However, at present, they generally tend to include children with special and/or complicated healthcare and medical requirements (24). In addition, some definitions also include children with special technological requirements and those suffering from ailments that restrict or even endanger their lives (24).

Impairments as well as activity limitations and restrictions all fall under the term “disability.” (25). Some children live with a single disability or need, however in more severe cases children may suffer from a mixture of physical, developmental, cognitive and affective limitations (26). Specific needs that notably affect the functioning and development of children include cerebral palsy, spina bifida, muscular dystrophy, spinal muscular atrophy, metabolic disorders and genetic syndromes (26). In the UK, it is common for the term “complex needs” to be applied, although this is interpreted varyingly by different institutions (27,28). Realistically, a significant number of children and youths, who indeed live with complex needs, cannot be easily classified into one specific medical or psychological category (27). This is attributable to the ambiguity in the

categorisation of conditions, and a lack of standard criteria defining numerous disabilities. Furthermore, one disability or need often has a bearing on another disability or need, meaning that children's learning and development is hampered to a notable degree (29).

According to the UK Equality Act (2010), a person is deemed to be disabled if they are recorded as having a long-term condition or impairment which significantly hinders their daily activities (30). By applying this definition, 8% of children in the UK are considered disabled, which amounts to around 1.1 million children (31). Meanwhile, approximately 17,000 UK families contain more than one disabled child, while approximately 6,500 families contain two or more (32).

The UK Disability Discrimination Act (1995) (DDA) classifies "disability" as a physical or mental deficiency with a long-term effect on a person's capacity to complete routine day-to-day activities (33). This term is applied to describe restrictions concerning function and activity that restrict a person's competence to carry out physical, cognitive, sensory and intellectual tasks (34)

The most frequently encountered form of needs among disabled children in the UK fall under the following categories (in descending order): social/behavioural (33%); learning disabilities (31%); and stamina/breathing/fatigue (31%) (31). Learning and mobility needs are sometimes put under the same category of developmental disabilities, which is a term designed to cover all needs connected with an enduring inability to reach developmental milestones (such as mobility and speech), carrying a substantial impact on day-to-day activities (35,36). Developmental disabilities also cover situations where a child is living with an impairment that negatively impacts daily functioning (e.g. cerebral palsy, ASD and Down syndrome) (36).

In Saudi Arabia, according to a national survey conducted among 60,630 children showed that around 6.33% children were reported as having some sort of disability. The Jizan region had the greatest proportion of disabled children (9.9 %), while Riyadh had the lowest (4.36 %). Physical disability was the most prevalent (3%), followed by intellectual disability (1.8 %) (11). Despite the rising attention in healthcare, research into the pattern of disability or needs in Saudi Arabia remains limited. Data about the characteristics, incidence and prevalence of children with SHCNs

in the Kingdom of Saudi Arabia are scarce (37). Additionally, information on dental health status of children with SHCNs is also limited with studies that show a high prevalence of oral disease among children without needs in the country (38–40). As result of the lack of evidence and the reported high oral disease among children, oral care providers must anticipate the needed oral care services for this group (41,42). More research that targets healthcare services for children with SHCNs are needed to plan for future special care services, implementation of primary prevention strategies, and proper allocation of health resources in Saudi Arabia.

The particular aspects of a child's life on which disability is determined include physical movement, cognitive and sensory functions, self-care, memory, self-control, and learning (21). Given the absence of a universal classification, however, this study considers a child with SHCNs to be a child with complex, special or additional healthcare needs attributable to chronic physical, cognitive, communication, and/or behavioural difficulties (1,27).

1.4 Oral health

The UK Department of Health defines "oral health" as follows:

> *"…the standard of health of the oral and related tissues which enables an individual to eat, speak and socialise without active disease, discomfort or embarrassment and which contributes to general well-being"* (43).

Meanwhile, the WHO provides the following definition:

> *"Oral health enables an individual to speak, eat and socialise without active disease, discomfort or embarrassment. Oral health is fundamental to general health and well-being, significantly impacting on quality of life. It can affect general health conditions. Oral health means more than healthy teeth. The health of the gums, oral soft tissues, chewing muscles, the palate, tongue, lips and salivary glands are also significant."* (44).

This definition of oral health stems from the WHO's following classification of health in general as *"a state of complete physical, mental and social well-being and not merely the absence of disease or infirmity"* (45).

Oral health is a very important aspect of general health, and in order to maintain overall health, it is important to consider maintaining good oral health at all times. This is particularly true for those with SHCNs whose susceptibility to oral disease is relatively high (46–48). Children with SHCNs have to tackle a variety of obstacles when trying to practice and maintain good oral health (49,50). It has been shown in the literature that children living with motor, sensory and intellectual needs struggle to perform oral hygiene practices (51–54). Other factors relating to the medical/health conditions of the child including age, degree of impairment(s), and living conditions can have a significant bearing on oral health (51–53). In terms of greater vulnerability to oral disease of those with SHCNs, the following factors are pertinent: abnormal tooth development and oral structure attributable to the child's particular medical condition; poly-pharmacy; a compromised immune system; poor access to oral care; and ongoing social and economic difficulties (55–57).

In some of the extant literature, children with SHCNs have been found to have poorer oral health, with a higher frequency of untreated caries and, ultimately, unmet oral needs (41,42). A substantial portion of research in this area has stated that children with SHCNs are more susceptible to dental diseases (50,58,59). Moreover, some studies have shown that children with SHCNs are 20% more likely to have dental requirements that go unseen compared to their healthy counterparts (60). Some of the nutritional factors that put children with SHCNs at greater dental risk include a higher intake of sugary medication, a propensity to eat softer food due to sensory processing, and the use of confectionary by family or carers to encourage children to gain weight or to steer their behaviour (61,62). In addition, a lower salivary flow, enamel deficiencies, dental crowding and lack of use of fluoridated toothpaste (61,63,64) can give rise to oral problems. Notably, some of the particular adverse outcomes that such children could encounter include systemic infections and hospitalisation (62).

1.5 Importance of Systematic reviews and randomised controlled trials

Systematic reviews are among the most important instruments in evidence-based practice, which itself is described as "the conscientious, explicit, and judicious use of current best evidence in making decisions about the care of individual patients" (65). Given the extensive amount of healthcare research published, the requirement for healthcare professionals to keep up to date with emerging evidence to ensure their evidence-based decisions are valid becomes increasingly difficult (66). Systematic reviews help to mitigate the problem of information overload, as they condense and appraise the literature by applying a systematic methodology to reduce bias and ensuring that decisions are properly informed (67).

Generally speaking, systematic reviews are scientific investigations that bring together evidence relating to a specific research question through the synthesis and critical appraisal of primary research results, and through the use of systematic, open, and replicable techniques to alleviate bias (68–70). The precise steps in carrying out a systematic review generally adhere to those enshrined in the Evidence-Based Practice (EBP) model (67).

The following are the most distinctive of these steps:

(i) Devise a particular research question according to the PICO (participants, interventions, comparisons, and outcomes) approach

(ii) Develop a clear and replicable protocol

(iii) Conduct a comprehensive search using a variety of detailed sources

(iv) Select studies according to the pre-defined eligibility criteria

(v) Thorough critical appraisal of the methodological rigour of selected studies

(vi) Synthesis of results by qualitative and/or quantitative (meta-analyses) techniques

(vii) Interpretation of the results (71)

This degree of rigour and openness is expected to improve the standard of the review, as there should be greater control over possibly systematic errors (72).

Systematic reviews, synthesising evidence from a comprehensive body of relevant primary research, are considered at the apex of the evidence hierarchy, especially when adhering to the "principle of total evidence" (i.e. the requirement to bring in all pertinent data to arrive at a valid decision) (73). Cochrane Systematic Reviews represent high-quality systematic reviews that are typically limited to the inclusion of randomised controlled trials (RCTs). Cochrane reviews provide a comprehensive and critical summary of what is known on a given topic, evaluating the effectiveness of health-care interventions for stakeholders such as healthcare consumers, providers and policymakers. Cochrane reviews are distinguishable from other systematic reviews due to their risk of bias tool. Specifically, this tool separates the concept of bias from methodological quality, believing it to be possible that research can still be of a good standard even if some risk of bias, specifically unavoidable bias, exists (74).

Randomised controlled trials are perceived to represent the "gold standard" of comparative research and are given priority accordingly (75). Importantly, a well-conducted RCT can minimise or in some cases eliminate bias (73). Bias, defined as "a systematic error, or deviation from the truth, in results and inferences," may trigger misinterpretation (i.e. under- or over-estimation) of the estimated true treatment effect, and could be the result of how an RCT is designed, carried out, or reported (67). Bias in research can diminish its validity, and ultimately the trustworthiness of the results, hence the importance of investigating the risk of bias in any given piece of evidence.

1.6 Importance of Clinical guidelines

In 1990, the US Institute of Medicine (IoM) classified "clinical guidelines" as follows:

> *"Practice guidelines are systematically developed statements to assist practitioner and patient decisions about appropriate health care for specific clinical circumstances"* (76).

In 2011, the IoM revised the definition as follows:

> *"Clinical practice guidelines are statements that include recommendations intended to optimize patient care. They are informed by a systematic review of evidence and an assessment of the benefits and harms of alternative care options"* (77).

By adding the clarification “clinical practice guidelines” the intention was to distinguish between preferred evidence-based type guidelines that are developed and reported in an open and methodologically robust manner, and other types of guidelines comparatively lacking in rigour (77).

Practice guidelines are frequently classified as documents in which recommendations are presented on either clinical practise or public health policy, assisted by a systematic review of evidence in which a review is undertaken on the positive and negative aspects of various intervention options (77–79). Pilling (2008) stated that clinical guidelines represent the most comprehensive tangible product of the evidence-based medicine movement (80). The WHO issues a handbook to guide policymakers, healthcare providers and patients, and sets out the implications (including resource implications) of opting for a given intervention (79).

In the UK, the three bodies at the forefront of devising clinical guidelines for dentistry are the National Institute for Health and Care Excellence (NICE), the Scottish Dental Clinical Effectiveness Programme (SDCEP) and the Scottish Intercollegiate Guidelines Network (SIGN). All have established very robust processes and have collected vast resources, which are shared on their respective websites and in their corresponding manuals. NICE guidelines are notable for their credibility and influence. Ultimately, guideline development programmes can serve as a means of driving evidence-based healthcare practise (80).

However, guidelines should be read with caution, acknowledging that the *methodological robustness in guideline development can vary*. Similarly, primary research and systematic reviews that often underpin guideline recommendations should not be unconditionally accepted, as the robustness of their methodological conduct and reporting may vary. A wise step here is to ensure that the development of guidelines is documented as transparently as possible and that a robust methodology has been applied to their development. The Appraisal of Guidelines for Research and Evaluation (AGREE) tool is useful in this regard. The AGREE checklist, which is a globally accepted standard, helps in terms of providing direction when assessing a guideline’s

methodological quality (81). Meanwhile, in the SIGN manual, another useful document, the AGREE checklist is presented, thus demonstrating its prominence in this sphere (82).

1.7 Justification for the focus of this project

Children with SHCNs live with a vast array of healthcare issues including oral health. Commonly, such children experience greater difficulty than their peers in accessing and receiving dental healthcare (83). Regardless of the advances to have been made in the availability of preventive care, there remain gaps across the healthcare spectrum, with shortcomings in dental health particularly pronounced (54,84).

This thesis aims to evaluate current guidelines on oral management for children with SHCNs and to determine the quality of evidence underpinning the recommendations made. It also seeks to assess the effects of different interventions for increasing the acceptance of LA, a common treatment reequipment in dental care for children and adolescents with and without special healthcare needs. Ultimately, this should help to secure a greater comprehension of children's care needs and the present clinical recommendations and evidence with regard to children with SHCNs.

Further, the thesis aims to investigate the parental perception of oral health care of children with SHCNs and to explore how oral care delivery is perceived by parents and caregivers across a broad context. It also seeks to qualitatively investigate how children with SHCNs are viewed in dental clinics, and how some negative attitudes are manifested in certain obstacles, discrimination and other disadvantages from the perception of parents and caregivers.

This topic is worthy of more attention because the number of children with SHCNs is growing (85). Gathering knowledge and information about various elements of care for such children will allow for a more comprehensive view of their actual care needs in the area of oral care. Overall, the aim of the project is to improve the standard of oral healthcare delivery for this increasing segment of society

1.8 Aims

The aims of this thesis are:

1. To assess the quality of guidelines using the AGREE II instrument, and to examine the underpinning evidence behind their recommendations on the management of oral care for children with SHCNs (chapter 3)
2. To assess the effects of interventions for increasing the acceptance of Local anaesthetic (LA), a common treatment reequipment in dental care for children and adolescents with and without SHCNs. (chapter 4, published in Cochrane Database of Systematic Reviews)
3. To assess parental perceptions and experiences of the delivery of oral care for children with SHCNs in Saudi Arabia (chapter 5)
4. To assess published systematic reviews and guidelines aimed at overcoming barriers to the delivery of oral care for children with SHCNs (chapter 6)

The thesis follows the University of Manchester's alternate format where chapters are presented in the style of a journal publication. The thesis is arranged in six chapters, written so that each chapter can be read independently.

In this thesis, special healthcare needs (SHCNs) is a frequently used abbreviation and serves to reinforce the definition used to steer the research. Otherwise, the terms "children with needs" or "children with disabilities" are applied where appropriate, usually in simpler contexts.

CHAPTER TWO

Children with Special Health Care Needs in Dentistry

2.1 Introduction

Oral health is an essential part of an individual's overall well-being. This is particularly true for children with SHCNs (SHCNs) as they are at an increased risk of developing oral diseases throughout their lifetime (22,62,86). Furthermore, children with special health care needs have additional oral health requirements that necessitate management in a dental care setting that has been adapted to their specific needs by an oral care provider with specialised knowledge and training. Dental care for children with special needs is still not considered a priority some in healthcare systems, despite calls for research into the optimum management of these children (87,88). Wright (1975) argue that it is crucial to invest in creating a positive attitude towards oral health services for children with SHCNs and to involve them in this process to aid ongoing prevention and improve oral health in the future (89).

This literature review aims to collect current knowledge regarding issues that could hinder or delay the delivery of appropriate and quality oral care to children with SHCNs. It also explores some of the treatment management options that could address the needs of these children when attending dental clinics. The special health care needs of children can arise as a result of intellectual, physical, social, or emotional impairment (63,85,90). Special healthcare needs are defined as:

> *"…any physical, developmental, mental, sensory, behavioural, cognitive, or emotional impairment or limiting condition that requires medical management, health care intervention, and/or use of specialized services or programs. The condition may be congenital, developmental, or acquired through disease, trauma, or environmental cause and may impose limitations in performing daily self-maintenance activities or substantial limitations in a major life activity."*(91)

Furthermore, as the population continues to grow, the demand for dental care for individuals with special needs also increases. As Polli et al. (2016) state:

> *"Once the expectation of population lifetime has increased, the demand for dental treatment for patients with intellectual disability, physical limitations, social and / or emotional deficit also grew."* (92)

According to a recent survey conducted among children who attend special support schools in England, 22% of five-year-old children and 29% of twelve-year-old children were found to have experienced dental decay (93). The increase in the percentage itself affirms the strong positive correlation between levels of dental decay and increasing age.

It is imperative that children who are more prone to caries receive preventive dental care (94). Those with SHCNs in receipt of such care will be more likely to have their oral health needs met (88,95). Several obstacles to preventive care exist, however, and these can include lack of access to dental care, lack of ability of dental professionals to care for children with SHCNs, lack of cooperation at dental appointments, oral aversions, other overriding medical needs and the financial and psychological burden on the child's family (50,62,96).

It should also be borne in mind that some children with SHCNs are often unable to grasp the importance of preventive oral health practices and/or will be unable to cooperate accordingly (97). In cases where the child is very young, where the child has serious conditions or where the child is accommodated in a care facility, the child's oral hygiene is the responsibility of whoever takes care of them. And this can be problematic when a parent or caregiver lacks knowledge and understanding about the significance of oral hygiene (98).

Thus, despite its clear importance, delivering good oral care to children with SHCNs can be fraught with difficulty (99). The challenges such children face are constant, and their serious oral needs often go untreated (100). Moreover, this population's ability to access necessary dental care can be hindered by the complex nature of their wider medical issues as well as behavioural problems and family's involvement in attaining proper oral care (100).

Children with SHCNs should, regardless of difficulty, be able to obtain good oral health, which includes an absence of pain and the capacity to consume and enjoy food (101). However, the reality

is quite different, with their healthy peers usually experiencing a significant advantage in relation to oral care provision (102). Although notable developments have been recorded in dentistry through the decades, the problem of delivering good oral care to children with SHCNs persists (58,103–105).

2.2 Provision of oral healthcare

Parents and caregivers of children living with SHCNs have claimed that healthcare personnel lack the required skills and knowledge to treat them properly. Indeed, a study found that people with special needs, compared to those without, were four times more likely to be frustrated with the care administered and nearly three times more likely to report being overlooked (12). It was noted by Lindsay et al. (2010) that persons with learning difficulties frequently fail to obtain necessary care (106).

Researchers have reported that some dentists find the delivery of care to children with SHCNs to be excessively difficult and stressful (107). With this in mind, Dao et al. (2005) indicated that:

> *"Health care for individuals with special needs requires specialized knowledge acquired by additional training, as well as increased awareness and attention, adaptation, and accommodative measures beyond what are considered routine"* (108).

However, certain dentists, whether due to time constraints or perceived insufficient remuneration, are not willing to administer care to such children (14). Casamassimo (2004) stated that only one dentist in every ten had treated children with SHCNs. As result, patients with special healthcare needs are more inclined to require curative, rather than preventive, treatment (107).

Smith et al. (2010) found that nearly three-quarters of special healthcare needs patients' trips to a dental practice were for emergencies and/or extractions. Significant obstacles to the administration of oral healthcare for special needs patients can be exacerbated by the patient's behaviour, the severity of their existing oral disease and the insufficient knowledge and skill of the dentist (Table 1) (109).

Given the complicated nature of their conditions and their sometimes unpredictable behaviour, a notable proportion of general dentists are neither willing nor suitably trained to deliver care to children with SHCNs (107,108). Even those dentists who have acquired proper training for special healthcare needs patients often tend to treat only a few children (110). In addition, Dougherty et al. (2001) noted that dental students obtained scarce training in caring for disabled patients (111). Meanwhile, Girdler et al. (2009) stressed that effective care for such patients would rely on a dentist's capacity to control the patient using suitable behavioural management methods, given that such patients, especially those with serious disabilities, may be incapable of cooperating (112).

In addition, the dentist may become a barrier when delivering oral care because of his/her inadequate knowledge and clinical experience. Dao et al. (2005), as well as Waldman and Perlman (2006) state that, apart from educational factors, several additional non-educational factors, such as adaptations to the clinical environment needed to provide dental care for these patients and concerns about adequate compensation also affect dentists' willingness to treat special needs patients (108,113). One study reports that many dentists failed to express an interest in the provision of dental care for children with SHCNs in their clinics, which could be related to a lack of confidence amongst dentists in managing these patients (114). Furthermore, one of the major problems in treating children with SHCNs is the lack of dental facilities that specialise in treating these children (90).

The number of paediatric dentists who provide care for children with SHCNs is increasing significantly, but despite receiving training in the provision of care for these children, many continue their practice with a standard approach for the care of all children (115). It is estimated that the total workforce who are trained and skilled in the provision of care to children with SHCNs is far less than is required, and therefore the capacity to offer dental services to those with SHCNs is extremely inadequate in the current situation (115). Consequently, the detrimental effects stemming from the current oral healthcare system necessitate analysis and improvement.

2.3 Oral healthcare of children with SHCNs

As previously stated, oral health is important for all children and especially for children SHCNs, who are more vulnerable to oral disease than other children (85,116). Children with SHCNs face many everyday challenges in maintaining good oral health (50,85). Delivering oral care is crucial for children with SHCNs, although in reality, it remains acutely challenging (99). Children with SHCNs often present with additional challenges both medically and dentally, which can often mean that obtaining appropriate dental care to meet their particular needs is difficult (100).

Delay in tooth eruption is one of the abnormalities that children SHCNs can encounter in their life; this delay can sometimes even extend to two or three years of age. Another anomaly is when a child has malformed teeth; this may lead to crowding or poor alignment of teeth, which is considered to be a general cause of dental issues such as gum disease and tooth decay (49). For children with learning disabilities or cerebral palsy, there is a high possibility that they will grind their teeth, which can cause the enamel to break down and cause more issues for the dentition (117).

Children with SHCNs resulting from brain injury or genetic conditions can suffer from seizures that put them at increased risk of traumatic dental injury, which requires further assessment and treatment (118). Furthermore, oral disease can be a consequence of prescribed medications or particular childhood behaviours. Medication with high sugar content is an additional concern, as this will result in increasing the chances of developing new oral diseases or worsening existing oral diseases (119). Furthermore, medications used to manage seizures can result in gingival overgrowth; other medications such as glycopyrrolate can result in xerostomia, which increases the risk of oral disease (49). Excessive tooth grinding habits during self-stimulation in children with special needs can result in further damage to the child's dentition, according to McPherson et al. (1998). It is also pointed out that patients with immunity suppression, due to conditions such as leukaemia or any other cancerous or cardiac condition, are at increased risk of various oral health problems (20). Kokhar et al. (2016) also posit that there would be a more significant challenge in the management of oral issues in children with special needs as some of these children lack an understanding of the importance of maintaining good oral health and also compliance towards the preventive measures (120).

2.3.1 Historical background for oral healthcare

Before World War II and immediately thereafter, there was no separate dental care focus or care for children with special needs. The provision of care was widely blended on account of: the widespread burden of dental caries; a lack of understanding of the additional health care needs of children with infectious and congenital disorders; and the considerable lack of knowledge and awareness in specialised dental practices (121).

It was in the late 1950s when awareness emerged, and interest grew amongst dental practitioners to form new approaches towards care for people with additional healthcare needs. It was during the same period that the Academy of Dentistry for the Handicapped was established, which later became known as the Academy of Dentistry for Persons with Disabilities (122). At the beginning of the 1960s, attention towards the disabled improved significantly. It was during these years that 'paediatric dentistry' took an active role in the provision of services along with other rehabilitative and medical practices, including a special focus on the care and requirements for special needs patients (121).

During the 1970s, the Robert Wood Johnson Foundation-funded educational courses in dental schools, which focussed on special and disabled patients; this was mainly prompted by the identification and recognition of the dental care needs of the disabled (122). However, it has been argued that these programmes were only marginally successful, as only a small percentage of graduates of those programs showed an increased acceptance of disabled patients in their clinics (122). Furthermore, most of the dental institutions that were participating in those courses failed, with only minor improvements and acceptance of these children during the period (122).

In the early 1980s, it became compulsory for British dental schools to integrate appropriate practices and approaches that would meet the requirements of patients with special needs into the curriculum in order to receive the accreditation standard (123). With this integration, a more complex focus was brought forth in the area of paediatric dental practices for children with special needs. Even though effective reforms were established in dental practices and institutions during this period, progress remained stagnant due to ineffective clinical and curriculum structures (123).

2.4 Issues relating to special healthcare needs children (SHCNs)

Dental issues tend to be more prevalent in the children with SHCNs population compared to the general population and as result, they might require additional preparations to meet their needs (60,124). In the UK, the first analysis of the numbers of disabled children with complex needs and life-limiting conditions in over a decade also estimated that numbers have increased sharply from 49,300 in 2004 to 73,000 in 2016 (125). Similar trends can be seen in other countries; data sources from the US National Survey of Children with Special Health Care Needs indicate that the proportion of children affected has increased from 12.8% in 2001 to 15.1% in 2010 (126).

According to a report published in 2009, it is estimated that 8.1% of the unmet needs in children with SHCNs will be dental care (124). Another study suggests that 77.1% of the general population have access to regular dental care of whom children with disabilities access dental care significantly less than other children (117). In addition, another study stated that 14.4% of patients with Intellectual Disability had not received any dental treatment in the preceding 5 years compared to only 8% of the general population (127). There is less chance of the decay being treated in children with learning difficulties, and in cases where treatment is applied, the likelihood of extraction is higher (128). This contributes to the aforementioned poorer outcomes for children with SHCNs, which could thus impact their self-confidence, nutrition, communication, and quality of life (129).

2.4.1 Issues in the Home

The presence of special health care needs in children may give rise to limitations in performing daily self-maintenance activities to maintain good oral hygiene such as tooth brushing. Due to limitations in their ability to perform oral hygiene activities caused to the severity of impairment, potential motor, and sensory and intellectual disabilities, children with SHCNs are prone to having poor oral hygiene (100). Consequently, the oral needs of children with SHCNs require specialised knowledge, increased awareness and attention, adaptation, and accommodative measures beyond

what is considered routine (130,131). In one study the author identifies that the entire challenge extends beyond the children present in the dental chair, but also to the needs of the families of such children as well (121).

Parents of children with SHCNs face many barriers during dental treatment, including, but not limited to, high costs of care and inefficient use of time (101,132). Children with SHCNs experience higher health care utilisation and expenditure than the average paediatric population. Chiri et al. (2012) reported that these children often use more hospital days, emergency room visits, surgical or medical procedures, medical specialist visits, and home health days than children without needs (132). This extensive use of services may create a financial burden for many families (133).

James et al. (1983) argue that an additional issue relates to the fact that families usually focus more on the medical treatment of the child, rather than his/her oral health (134). Children with needs may also express greater anxiety about dental treatment than those without a disability, which could delay appropriate dental treatment and lessen their cooperation (135). All of these barriers can impede the chances of children with SHCNs receiving adequate oral care.

2.4.2 Issues with Oral Healthcare Provision

An investigation was conducted by Mahon and Kibirge (2004) into the frequency of and reasons behind children with SHCNs being referred to a paediatric assessment unit in the UK from 1997 to 2001. The study showed that children with SHCNs were admitted to hospital more frequently and for longer periods compared to their peers without needs (16). Meanwhile, Cooper et al. (2004) asserted that people with special healthcare needs placed a notable burden on healthcare systems (136). Elsewhere, Newacheck and Inkelas (2004) carried out a study to gather more information about the healthcare experiences of children with SHCNs, revealing they were hospitalised four times more often than their healthy counterparts (13).

In the entirety of dental management literature, there is comparatively little information and data on the current challenges or systematic obstacles to the treatment of children with SHCNs (39).

However, Stiefel (2002) suggests that five principal issues persist globally in oral healthcare systems for patients with special healthcare needs, irrespective of their age group (137). These are:

1. Lack of, or sometimes lack of, an integrated delivery system
2. Lack of academic and regional treatment facilities and institutions
3. Limited opportunities within a facility to provide interdisciplinary training
4. The necessity to integrate structured and systemic oral health
5. The non-awareness of dental-caregivers (137).

Stein (2001), in his work '*Challenges in long-term health care for children'*, asserts profound institutional issues persisting in the oral health care management towards children with SHCNs. He raises not only issues arising from the healthcare system, but also patient issues in the long-term care of children with SHCNs (138). The entire context, as projected by Stein (2001), is shown in Table 2 below. It is important to comprehend the very fact that the difference and the isolated nature of dental practice would differentiate it from general health practice. However, in most cases, the standard of practice ethics and rules of dental practice in most countries compel practitioners to attend to the needs of these children (Table 1) (138).

Issues in the system	Examples occurring in the oral healthcare delivery system
Dependence on Technology	When the patient is confined to bed or wheelchair When the patient is respiratory dependent Prompting more than one visit, due to gastronomy feeding
Dependence on Caregiver	Oral health care and the delivery of home health activities are affected due to the blurring of roles Dire lack of clarity when it comes to consent, payment and other problems mainly related to the care service
Dire lack of proper definition when it comes to oral health care	Issues in the reimbursement system and the denial of medical requirements that would affect the correct development and facilitation of rehabilitation Issues pertaining to the focus of oral healthcare sub-departments, such as dietary modification, oral surgery and even sometimes physical therapies.

Dire lack of adequate services	Oral health interventions that are under-skilled (for example, healthcare offered by non-dentist practitioners) Insufficient approval towards special oral health care practices (for example, general anaesthesia covering the restorative care) Inappropriate services and practices getting approved (for example, paying for lingual frenectomies)
Care in the financing section	Limitation in covering various special requirements Low payment system for various dental procedures in public programs
Care Delivery Models	Institutional dental services that are poor in quality Improper coordination of the dental service with other general health departments Dire necessity in the special oral health expertise Inappropriate transition to adult health care
Issues in the quality of the dental service system	Inappropriate or improper quality management system, standards and measures

Table 1: Issues in the system that affect the oral health care of CSHCNs

These major obstacles for oral care providers are mainly due to the inadequate system and services available in mainstream dental care facilities to treat these children (121).

Access

In general terms, children with SHCNs suffer from the limited availability of healthcare services (3,139). Given their special and particular healthcare requirements, they are reported as needing healthcare more than those without conditions (3). Indeed, studies have revealed that children with SHCNs have more substantial healthcare needs compared to their peers (140–142). In a study investigating the quality of hospital care for individuals with learning disabilities in the UK, Glasby (2002) determined that certain people with learning needs were not getting the right standard of care and that health services were frequently insufficient and unresponsive to meet their needs

(143). Evidence obtained at national and international levels shows that many disabled patients find mainstream services to be inadequate, something that has been admitted in a 2012 NHS report (144). This was reinforced by government demands to make enhanced healthcare for persons with special healthcare needs a top priority (145).

Despite these governmental priorities, children with SHCNs still find it particularly challenging to access oral care services as a result of their complex condition, transportation issues, limited numbers of dentists with the necessary expertise, area of residence and parental education (146). One study reported that up to 25% of parents of children with autism had experienced some difficulty in accessing oral care for their children (147). In addition, Nelson et al. (2011) reported that 9% of parents and caregivers of children with SHCNs considered it difficult to travel to the oral care provider and that 15% had experienced difficulties in accessing dental care even in clinics close to their area of residence (50).

Accessible dental care presents significant challenges to many children with SHCNs families (20). Barriers in access to dental care for children with developmental needs have also been reported, with transportation difficulties and overall workforce capacity shortages the most commonly encountered obstacles (148). Nevertheless, dental care is consistently listed as an essential service by parents for their children with disabilities of all ages (39).

It is not only the issues pertaining to the healthcare system that the oral health sector faces, but also the patient-related obstacles or challenges that they may encounter that also affects the entire service. When it comes to patient-related challenges, it includes the characteristics that define CSHCN or, in another case the healthcare delivery system aspects that are ordinarily designed for patients without any disability, which becomes ineffective in treating the CSHCN (Table 2) (121).

Issue Areas	Examples of the Issues
Accessibility	Institutions that are considered difficult to access physically Institutions that are not situated on the transportation route Institutions that do not have the facility to accommodate special needs, which also creates scheduling problems
Financial	Institutions that do not have special needs medic-claim policies Institutions that are unaware of secondary or alternate funding resources Low-quality training and sometimes underemployment
Psychosocial	Complex health problems Fear to receive or approach healthcare Socially deprived Low intellect Lesser priority in oral health
Stability and Mobility	Movements that are uncontrollable Weaknesses in the muscles Short focus span Hyperactivity
Communication	Speech, sensory or intellectual disability
Medical	Special medication Allergies Atypical cognitive ability

Table 2: Issues relating to special healthcare needs patients (121).

Referrals

General dental practitioners in the UK usually provide dental services for children with SHCNs, and they mostly refer those patients with treatment needs beyond their skillset and expertise to Special Care Dentistry or Paediatric Dentistry services. It is uncommon in the UK for children to have direct access to specialist services unless they are first seen by a primary dental care practitioner (149). Paediatric Dentists typically focus mainly on the treatment of children who

require additional care and attention, while Special Care Dentists (SCD) are concerned principally with the improvement of oral health conditions for children with SHCNs. Furthermore, Special Care Dentistry services in the UK are often provided through hospital settings and across the community, which is more convenient for the children (149).

Lack of Specialists

There has been little improvement in the treatment of children SHCNs in recent years, and therefore, by assessing the current literature relating to dental practise, it becomes clear that only a small percentage of dental practitioners and the associated workforce have made an effort to acquire the awareness and knowledge to treat children with SHCNs. Casamassimo (2014) asserts, "only small percentages of dental practitioners make CSHCN a portion of their practice" (121). Within this scenario, the majority of paediatric dentists became default practitioners for all children, including children with special needs (150). For this reason, many paediatric dentists lack the necessary specialisation in treating children with special needs. This results in dentists' poor communication skills and a lack of knowledge when treating children with uncontrollable movements (151).

Lack of Training

Comparatively, the proportion of dental care teams who show an unwillingness to attend patients with special health care needs is increasing (152). One of the main reasons for this unwillingness is the lack of awareness and specialist knowledge to approach patients with special health care needs, followed by discomfort from treating patients with special health care needs (137).

These two issues have consistently been asserted in this field for a prolonged period and confirm that ineffective dental education contributes to the community of dental practitioners who are unwilling and unskilled to care for children with SHCNs. Even though there is a significant challenge for parents and dental professionals to manage children with SHCNs, it is also important

to signify the inability of these dental professionals to manage these kinds of complex situations (153).

According to Lehl (2016), the main reason behind this inability is the lack of proper knowledge, education, experience, and training (154). This position was affirmed recently by a study of a large number of ADA members, who reported that general dental practitioners are unwilling to treat patients with special health care needs, citing a lack of appropriate training, knowledge and awareness (109). Specifically, Smith et al. (2010) stated that, among all the dental schools, only a few provide facilities for activities that focus on the special need's patient, and consequently the lack of willingness on behalf of the practitioner is unsurprising. It is indeed not straightforward to train general dentists in the care of children with SHCNs, and the same is true for paediatric dentists. Meanwhile, it is also important to understand that by providing dental care for the children or patients with special needs, there is no extra financial gain for these teams. This may be one of the main reasons for these professionals to remain unskilled or otherwise choose to be unskilled in these areas. However, Lehl (2016) points out that the experience gained through these situations becomes long-term assets for the practitioners and professionals in these areas. Patients with special healthcare needs, especially children, sometimes undergo the same procedures as non-special needs patients, but more time and effort needs to be given to successfully complete the procedure.

Providing a routine dental assessment can be challenging for dental care professionals for a variety of reasons, including: gaps in, or absence of, professional training; limitations in the working environment; difficulty in adaptation due to the change in the environment; the lack of specialist equipment; or lack of proper scientific knowledge relating to the patient and the condition Krause (148,155). These factors can occur alone or in combination.

There have been many suggestions made to improve the situation, which consider the many past experiences of treating members of such categories. The suggestions include improved training for the undergraduate and the postgraduate dental student, increased access to training for

qualified practitioners, and discretionary fees to the practitioner to compensate for the additional time required for dental appointments (156). The needs are currently being addressed by the Teachers Group of British Society for disability and oral health in the UK, and they have led to new clinical education plans and development programs for undergraduates in the dental unit (51).

Due to the increased health care utilisation, many dental schools around the world are enhancing and restructuring their curriculum, and this includes changes to accommodate the dental management of Children with SHCNs (121). A large number of health care providers, professionals, policymakers, families, and other concerning individuals have enforced the improvement in the oral health care system for Children with SHCNs and also put in significant effort to ease the challenges in accessing oral health (157).

2.5 Conclusion

Children with SHCNs often present with several medical and oral conditions, and the existing lack of understanding from all stakeholders in relation to their specific requirements can interfere with the delivery of optimal oral care. One area of improvement in the quality of care for children with SHCNs is the presence and the development of clear clinical guidelines, aiming at providing the best oral health practice to manage and consider those children in dental setting properly. All efforts should be incorporated to support this demographic, as different forms of management and treatment approaches become available and can be utilised to allow children with SHCNs to receive the correct and necessary dental treatment required.

CHAPTER THREE

Assessing the Quality of Clinical Guidelines on Oral Health Care for Children with Special Healthcare Needs

3.1 Abstract

Background: Robust evidence-based guidelines are important in everyday clinical practice, especially when delivering and managing oral care needs to a vulnerable group such as children with SHCNs.

Aims: To assess the quality of guidelines on the management of oral care for children with SHCNs.

Methods: To find appropriate guidelines, an electronic search of MEDLINE Ovid was carried alongside an additional search of common guideline websites. The AGREE II tool was used to assess the quality of the guidelines. Assessment was undertaken independently by three assessors. Furthermore, the underlying evidence used to formulate recommendations in the identified guidelines were qualitatively assessed.

Results: There were nine guidelines, with 41 recommendations, that met the eligibility criteria. The quality of the guidelines was generally found to be poor. Only one guideline was assessed as 'recommended' by the three assessors, based on the quality of the methods, reporting, or both. Only two of the 41 sets of recommendations, made across the 9 guidelines, were judged to be valid and based on a rigorous systematic review of the evidence.

Conclusions: The current state of guidelines on oral care management for children with SHCNs is, on the whole, of very low quality. The scientific community should work together to enhance the quality and strength of the current clinical guidelines and to ensure that they are trustworthy prior to implementation.

3.2 Background

Oral health conditions for children with SHCNs are often poorer when compared to healthy children (47). Oral health is a very important aspect of general health, and in order to maintain overall health, it is important to consider maintaining good oral health (48). Specifically, children with SHCNs face many everyday challenges or problems in maintaining good oral health (50,85). This group of children often present additional challenges, such as complex medical conditions and behavioural issues, which can result in more difficulties in obtaining appropriate dental care (100). Many research studies have reported that people with SHCNs are at a higher risk of dental diseases compared to others, and are also more likely to have untreated or unmet dental or oral needs - almost 20% more than other individuals (44, 54, 56).

Receipt of optimal oral health care is fundamental for children with SHCNs as it can provide them with confidence, thereby allowing them to reach their full potential, as well as take part in society. Providing children with SHCNs with appropriate oral health care necessitates additional treatment and care from all health workers, where they take into consideration the physical and medical limitations of the child. One important aspect of achieving reasonable oral health care for children with SHCNs is the development of clinical guidelines to address the needs of this population in a dental setting. Moreover, guidelines are intended to assist oral health providers and clinicians in planning, as well as in delivering, the highest-quality health care.

According to the Institute of Medicine (2010), guidelines are

> *'systematically developed statements to assist practitioner and patient decisions about appropriate health care for specific clinical circumstances'* (77).

The clinical guidelines can also play a significant role in the formation of health policy and have evolved to encompass subjects and issues across the field of health care (158).

Guidelines are mainly aimed at providing oral health practitioners and clinicians with a set of explicit recommendations and suggestions regarding how to deal with certain situations, as well as to minimise the use of harmful, ineffective or unnecessary actions or measures. Those developed

recommendations should be the result of a long process of consideration of valid and up-to-date evidence for the correct management and treatment of the dental patient. By reducing inconsistencies and variations between clinical practice and scientific evidence, clinical guidelines can enhance the quality of dental care that is delivered to the patients. Guidelines should be rigorously developed and precise, ensuring that any resulting recommendations are clear and reproducible (81).

Several factors can limit the usefulness and/or the applicability of clinical guidelines. These include the guideline development methodology, the availability of sound research evidence, the uniqueness of individuals, and how the research findings can be generalised. On that basis, guidelines for the management of oral health in children with SHCNs should be appraised as it is very important to identify and analyse any potential flaws in their development (158,159). Indeed, different appraisal tools have been developed to determine the quality of clinical guidelines (81).

The AGREE II tool is an instrument that is used widely for the assessment of transparency, accuracy, and methodological rigour of guideline development, and has been tested for its reliability as well as validity. The AGREE II tool is to be applied or used by guideline developers to properly guide their work and to evaluate or assess the quality of their methodology (The AGREE Collaboration). Through its process, the AGREE II tool makes use of a detailed framework to assess the quality of guidelines. In addition, it also offers a preferred methodological framework for the development of content for the guideline. This instrument has been designed and developed to assist in the standardised and objective appraisals of guidelines, as not all clinical guidelines are developed or conducted transparently and rigorously (81).

3.3 Objective

The aim of the current study was to critically appraise the most recent guidelines on oral health care management for children with SHCNs in a paediatric dentistry setting, using the AGREE II tool. A secondary objective was to evaluate the underpinning evidence behind the recommendations listed in the appraised guidelines.

3.4 Methods

The AGREE II instrument was used in this study to critically evaluate clinical guidelines for the treatment and care of children with SHCNs in a paediatric dentistry setting.

Eligibility Criteria

A review of the literature was undertaken to identify clinical guidelines and recommendations focusing on oral health care and treatment of children with SHCNs in dentistry. We included guidelines that met all of the following inclusion criteria:

- Guidelines published in the English language and within the past ten years
- Only guidelines listed for specific or particular clinical circumstances or conditions for children and with SHCNs related to oral health care were included
- Only guidelines intended for or directed towards practitioners to assist in handling, as well as treating oral health for children with SHCN in paediatric dentistry were included

The exclusion criteria for the guidelines were:

- Guidelines that have been superseded or modified by a more recent version carried out by the same group of guidelines developers
- Guidelines that were reproduced versions of previous or current guidelines and have not been reproduced with amendment

Information Sources and Search Strategy

A search of the MEDLINE Ovid database was conducted using the search terms that are shown in Appendix 1.

Additionally, the following websites were searched thoroughly to find clinical guidelines for children with SHCNs in dentistry:

1. The National Institute for Health and Care Excellence (NICE) (https://www.nice.org.uk/)
2. The Royal College of Surgeons of England (https://www.rcseng.ac.uk/)
3. The British Society of Paediatric Dentistry (http://bspd.co.uk/)
4. The Scottish Dental Clinical Effectiveness Programme (SDCEP) (https://www.sdcep.org.uk)
5. British Society for Disability and Oral Health (http://www.bsdh.org/)
6. American Academy of Paediatric Dentistry (http://www.aapd.org/)
7. Special Care Dentistry Association (http://www.scdaonline.org/)
8. US National Guideline Clearinghouse (https://www.guideline.gov/)

Selection of Guidelines

One assessor examined and evaluated the titles as well as the abstracts of each of the retrieved records to determine which ones were appropriate and should be selected as per the eligibility criteria. If the retrieved records were not clear from the titles and abstracts, a full-text copy was checked for any potential eligibility.

Guideline Assessment Using the AGREE II Instrument

The AGREE II instrument aims to provide a framework to assess or analyse the quality of clinical guidelines; to provide a procedural and systematic strategy for guideline development; and to inform or explain the preferred content and the reporting of the content in clinical guidelines. The AGREE II instrument is comprised of 23 key items within six domains, with two additional global rating items. The six domains are as follows:

1.1 **Purpose and Scope:** This domain is concerned with the guideline's overall aim, the target population, and the particular health-related questions (items 1-3).

2.1 **Stakeholder Involvement:** This domain lays focus on the extent or degree to which the guideline has been developed or formulated by the appropriate or right stakeholders and denotes the opinions of the intended users of the guideline (items 4-6).

3.1 **Rigour of Guideline Development:** This domain relates to the process that is used to gather, as well as produce the evidence; the various methods that are used for formulating or developing the recommendations; and to update or apprising them (items 7-14).

4.1 **Presentation of Clarity and Transparency:** This domain deals with the guideline's format, structure and language (items 15-17).

5.1 **Applicability of Guidelines:** This domain relates to the possible facilitators and barriers to implementation, approaches to enhance uptake or acceptance, and resource implications and consequences of guideline application (items 18-21).

6.1 **Editorial Independence:** This domain focuses on the formulation or development of recommendations without any bias (items 22-23).

All 23 items, across the six domains, are rated on a 7-point scale

Score of 1 (*Strongly Disagree*) - given when there is no information that is relevant to the AGREE II item, if the concept is very poorly reported, or if the authors state explicitly that criteria were not met.

Score of 7 (*Strongly Agree*) - given if the quality of reporting is exceptional and where the full criteria and considerations articulated in the User's Manual have been met.

A score was assigned based on reporting quality and completeness. A score between two and six was given when the reports of the item failed to address all the item considerations or full criteria.

All guidelines meeting the inclusion criteria were rated independently by three appraisers to increase the reliability and accuracy of the assessment. A pilot exercise was undertaken by the assessors to establish consistency in the scoring process. It is important to note that a level of subjectivity is required in rating the guidelines. The considerations as well as the criteria are there for guidance and direction, not for replacing or changing these judgments. Therefore, none of the items in the AGREE II instrument offered explicit expectations and outlooks for each point on the 7-point scale.

An overall assessment using the AGREE II instrument involves two additional items, the first was to ask the appraiser to judge the overall quality of each of the reviewed guidelines on a 1 to 7 scale,

and the second was to ask the appraiser if they would recommend the use of the guideline, with *yes*; *yes with modifications*; and *no* as the three possible responses.

Calculating the Domain Scores

A quality score was calculated for each of the six domains in AGREE II by totalling the scores of the domain's items and by scaling the total score as a percentage of that domain's maximum possible score, as described in the AGREE II User's Manual. All the six domain scores were independent and therefore were not aggregated into one quality score.

$$\frac{Score\ obtained - Minimum\ Score\ Possible}{Maximum\ Score\ Possible - Minimum\ Score\ Possible}\ x\ 100$$

For a domain with three items, appraised by three assessors:
Maximum score that is possible for this domain (63) = 7 (strongly agree) x 3 (appraisers) x 3 (items)
Minimum score that is possible for this domain (9) = 1 (strongly disagree) x 3 (appraisers) x 3 (items)

3.5 Results

3.5.1 Guideline Appraisal with AGREE II

From the literature search, a total of 314 records were identified. From an initial screening, 28 guidelines were identified for further review, of which nine guidelines were deemed eligible for inclusion. These nine guidelines were critically appraised using the AGREE II instrument. The overall results are presented below in Tables 2 and 3. Furthermore, the median and the range scores for each domain were reported in Table 3 to summarise the overall result of the included clinical guidelines.

	AGREE II DOMAIN							
Guideline	Scope and Purpose (%)	Stakeholder Involvement (%)	Rigour of Development (%)	Clarity of Presentation (%)	Applicability (%)	Editorial Independence (%)	Overall Assessment (median) (%)	Would you recommend? (%)
Guideline on behaviour guidance for the paediatric dental patient (160)	67	31	36	56	19	0	4-4	N, N, N
Clinical holding skills for dental services (161)	80	28	3	35	15	0	3-4	N, N, N
Clinical guidelines and integrated care pathways for the oral health care of people with learning disabilities (162)	81	83	59	69	31	0	4-4	N, N, N
Guideline on use of anesthesia personnel in the administration of office-based deep sedation/general anesthesia to the pediatric dental patient (163)	80	28	29	57	10	0	3-3	N, N, N
Guideline on management of dental patients with special health care needs (165)	85	28	24	67	15	0	3-4	N, N, N

Guidelines for monitoring and management of paediatric patients before, during, and after sedation for diagnostic and therapeutic procedures (166)	74	17	10	43	7	0	3-3	N, N, N
Guideline on use of nitrous oxide for paediatric dental patients (167)	78	26	28	63	17	0	3-3	N, N, N
Guideline on prescribing dental radiographs for infants, children, adolescents, and persons with special health care needs (168)	81	24	22	69	0	0	3-4	N, N, N
Use of silver diamine fluoride for dental caries management in children and adolescents, including those with special health care needs (169)	85	72	88	85	60	0	6-6	Y,Y,Y

Table 3:The overall scores for each included guideline by the AGREE II domain

The overall assessment is the median of the three appraisers; score of one indicates the lowest possible score to seven, the highest possible score
Y = yes, Y+ = yes with modifications, N = no.

Domain	Median score (%)	Range of scores (%)
Scope and Purpose	80	67 to 85
Stakeholder Involvement	28	17 to 83
Rigour of Development	28	3 to 88
Clarity of Presentation	63	35 to 85
Applicability	15	0 to 60
Editorial Independence	0	0 to 0

Table 4: Summary scores for each domain by the AGREE II tool

The assessors' ratings provided in Table 4 suggest that according to the AGREE II instrument, guidelines on oral health care for children with SHCNs are typically of low quality. This was perhaps best demonstrated by the fact that all assessors would only recommend one of the nine guidelines. Following the AGREE II User's Manual there is no guidance as to thresholds for high or low quality, and that the end-user should use their judgment for interpretation. For all the domains, a cut-off score of > 60%, which has been used in the literature before, was used in this study to indicate a high-quality guideline (170).

The first domain, 'Scope and Purpose', generally scored well, with the median score across the nine guidelines of 80% (range 67 to 85%). All the included guidelines scored greater than 60%. However, clinical guidelines are likely to score high in this domain, as this is a fundamental part of the guideline development process. Meanwhile, the second domain, 'Stakeholder Involvement', generally fared less well, with a median score of 28% (range 17 to 83%), and only two guidelines scored greater than 60% (162,169). Furthermore, in this domain, the views and preferences of the target population (item 5) had not been sought or discussed across the guidelines, except for the two-aforementioned guidelines.

The third domain, 'Rigour of Development', was judged as poor, with a median score of 28% (range 3 to 88%) and with only one guideline that scored > 60% (Crystal et al., 2017). All the included guidelines had noticeably low scores across all items in the 'rigour of development' domain, especially items 13 (external review of the guidelines) and 14 (guideline updating procedure provided). In addition, we judged the fourth domain, 'Clarity of Presentation' to be poor for four guidelines, which scored <60% with a median score of 63% (range 35% to 85%). Furthermore, a high score in this domain by presenting the recommendations in a clear format should not be too difficult to achieve, however four guidelines fell short in this area (160,161,163,166). For the fifth domain, 'Applicability', the majority of guidelines were judged to be poor, with a median score of 15% (range 0% to 60%), and only with one guideline scoring > 60% Crystal et al., (2017) (169). Even though the guidelines were developed largely by professional organisations such as the American Academy of Paediatric Dentistry AAPD, all the included guidelines, except for the Crystal et al. (2017), failed to consider and report guideline implementation (169). The final domain, 'Editorial Independence', scored extremely low with a score of zero across all guidelines. Looking at the scores of this domain no clinical guidelines included explicit statements regarding independence and any competing interests arising during the formulation or development of their recommendations.

3.5.2 Appraisal of Underlying Evidence

When inadequate focus is applied to the underpinning evidence in guidelines, there is a chance that incorrect recommendations may be given, subsequently leading to clinicians' performance being potentially less than optimal for their patients. Recognising the relevance and quality of the underpinning evidence can of course mitigate such negative outcomes. The majority of guidelines do not take into account the extent to which evidence can be generalized for people, interventions, and outcomes (171,172). Whilst applying the AGREE II instrument it became clear that at no point were queries raised as to the quality of the evidence that underpinned the guidelines. To complete this chapter on guidelines for the management of oral care for children with SHCNs, it was important to examine/ appraise the underpinning evidence in the included guidelines.

The main researcher, with a background in the topic covered in the included guidelines, documented the recommendations and underlying evidence cited by each guideline. Striving for an objective review, all guidelines were thoroughly investigated to determine whether high-quality evidence (systematic reviews) had been used as the foundation for any recommendations by appraising the references presented. References to systematic reviews were examined independently and in duplicate to determine the quality and the relevance of the underlining evidence.

Guideline	Population	Condition or type of intervention (prevention, diagnostic test, and treatment)	Grade or level of recommendation(s)	Recommendation(s) supported by high-quality evidence?	Comment
Guideline on behaviour guidance for the paediatric dental patient (160)	Paediatric dental patients (behaviour guidance)	Behavior management	None stated	No	The recommendations listed were based on a narrative review of the literature (not a systematic review). This guideline only referenced one systematic review and it is not related to the final recommendation.
Clinical holding skills for dental services (159)	Specific to children with disabilities	Clinical framework	None stated	No	This is a framework for using restrictive interventions. Not clear how the evidence was searched and how recommendations were formulated. This guideline does not cite any systematic reviews.
Guideline on use of anesthesia personnel in the administration of office-based deep	Paediatric dental patients	Regulatory measures for pharmacological management	None stated	No	The recommendations listed were based on narrative reviews of the literature. Very vague recommendations that do not reference any systematic review.

sedation/general anesthesia to the pediatric dental patient (161)		(deep sedation/general anesthesia in clinic)			This publication aims to provide a list of regulatory measures for using pharmacologic behaviour guidance in dental setting.
Clinical guidelines and integrated care pathways for the oral health care of people with learning disabilities (160)	Specific to individuals with disabilities	Prevention of oral diseases and the maintenance of good oral health	SIGN grading levels A, B or C. Grade A (at least one randomised controlled trial); B (conducted clinical studies but no randomised clinical trials on the topic of recommendation); C (Requires	Unclear	No systematic review(s) were used to inform this guideline. Recommendations were listed without referencing the individual body of evidence. (recommendations were labeled using SIGN grading levels but not linked to the specific body of evidence).

			evidence from expert committee reports or opinions and/or clinical experience of respected authorities).		
Guideline on management of dental patients with special health care needs (163)	Specific to individuals with SHCNs	Management of oral health care needs for individual with SHCNs	None stated	No	The recommendations listed were based on a narrative review of the literature (not a true systematic review). The guideline only references one systematic review, and it is not related to the final recommendations. The recommendations are vague and general with only four of the recommendations are related to children with SHCNs.
Guidelines for monitoring and management of paediatric patients before, during, and after	Paediatric dental patients	Safety and management measures of	None stated	No	The recommendations listed were based on a narrative review of the literature (not a true systematic review). This publication aims to

sedation for diagnostic and therapeutic procedures (164)		sedation			provide an updated statement to unify the guidelines for sedation, however, the recommendations are vague and general. The guideline did not reference any systematic review.
Guideline on use of nitrous oxide for paediatric dental patients (165)	Pediatric dental patients	Practical aspects of delivering Nitrous Oxide	None stated	No	The recommendations listed were based on a narrative review of the literature (not a true systematic review). Although the guideline specifically mentions children with SHCNs as indication to use this treatment, there were no specific recommendation or measures that listed this population. Very vague recommendations that overlap with the previous guidelines referenced (documentation, monitoring, facilities/personnel/equipment…). The guideline dose not reference any systematic review.
Guideline on prescribing dental radiographs for infants, children,	General and specific to patients	Timing and prescribing of	None stated	No	The recommendations listed were based on a narrative review of the literature (not a true

adolescents, and persons with special health care needs (166)	with SHCNs	radiographs			systematic review). Although the guideline specifically mentions patients with SHCN, there was no specific recommendation to this population. The guideline does not reference any systematic review.
Use of silver diamine fluoride for dental caries management in children and adolescents, including those with special health care needs (167)	General and specific to children with SHCNs	Treatment and application of Silver Diamine Fluoride	(GRADE) approach was used	Reference one systematic review in 2016 with 4 RCTs	The guideline is largely informed by an existing systematic review (Zhao, 2016). It is also informed by other guidelines, clinical studies and expert opinion. (Authors conclude that there is very low-quality evidence (GRADE) none of which included children with children with SHCNs).

Table 5: Baseline characteristics for the guidelines

Overall, 41 sets of recommendations were reviewed in the included guidelines. Naturally, some guidelines dealt with multiple conditions rather than just one. The most frequently mentioned issue was the use of general anaesthesia, sedation, and behaviour management of children with SHCNs (in 7 of the 9 guidelines). This was followed by the use of clinical holding and the use of fluoride. Among the recommendations reviewed, only two were deemed to be sufficiently supported by a high-quality systematic review. Furthermore, the recommendations in just two of the reviewed guidelines had been allocated a grade/level the remaining guidelines failing to do so.

3.6 Discussion

It is important to acknowledge that certain limitations in the review process may have had an impact on this guideline appraisal work. Firstly, it is important to emphasise that despite our best efforts, this was not a comprehensive or exhaustive assessment of clinical guidelines in relation to oral health care for children with SHCNs. Some clinical guidelines may have been missed as a result of human error or due to the electronic search strategy. Some clinical guidelines do not include children with SHCNs in their headings or abstracts as a potential beneficiary, which makes it challenging to identify potentially eligible guidelines. Further, guidelines are rarely indexed and not always published making their identification and retrieval difficult. For guidelines to have any chance of improving clinical practice, as is their primary intention, they need to be easily accessible.

The AGREE II tool has certain limitations in the search for quality evidence that underlines the final set of recommendations in a guideline. The AGREE II instrument cannot highlight such a deficiency, as the focus on methodological issues that are linked to guideline development is insufficient to ensure that the final set of recommendations are valid. Hence, this tool is used to evaluate the process of guideline development and the way it is reported (173). Furthermore, by working through the appraised guidelines it became apparent that the supporting evidence underpinning the final recommendations was based on evidence of variable quality. This is due to the fact that most guidelines failed to incorporate high quality and valid evidence such as a systematic review in some or all the final sets of recommendation, and thus, requires further investigation.

Using the AGREE II tool, most guidelines had the highest scores in the domain, 'Scope and Purpose'. Indeed, this had been anticipated, as this domain is comprised of fundamental components of a guideline that cannot be easily neglected, such as the target population, the health questions that are being addressed, and the objectives of the guidelines. Therefore, guideline developers usually focus more on these parts of the guideline when developing their papers.

Participation in or co-development of guidelines was especially limited, as indicated in the domain, 'Stakeholder Involvement'. Only two clinical guidelines included members belonging to other professional groups as developers of guidelines (The Royal College of Surgeons of England, 2012; Crystal *et al.*, 2017) (162,169). Furthermore, the views of the patients were not taken into consideration in the development of the clinical guidelines, but rather the patients/public participated as external reviewers after the guidelines had been developed, except for the two aforementioned guidelines. This speaks poorly of the developers of guidelines in the field, as it is very important to consider the views of those for whom the guideline is developed, which may also help later on in the successful implementation of the guidelines (174).

The 'Rigour of development' domain is a strong indicator of the quality of clinical guidelines, as it represents the methodology part as compared to other domains. A high score in this domain indicates that the guideline has been developed with minimum bias and is based on evidence, whereas a low score, on the other hand, indicates potentially serious problems in the methodological approach that is used for the development of guidelines (175). However, all the included guidelines, except for one, had incomplete or entirely missing methodological details, such as the presence of external inputs by experts prior to the guidelines' publications, and including a timeline for the guideline updating process (169). Furthermore, guidelines need to reflect the current literature and provide a revision or updated procedure in the guideline's development, which is a fundamental step in the identification of new evidence that may impact existing recommendations. Guidelines can become outdated as new evidence emerges, and therefore developers should prospectively determine when and how they will update a

guideline. In the appraised guidelines, most were missing a statement regarding the process for updating the guideline process, except for two (162,169).

Guideline developers in paediatric dentistry make use of rigorous methods that include the participation and opinions of all the relevant stakeholders. It is also important that clinical guidelines should have a detailed and structured approach in order to assess the quality and evaluate the strength of evidence that they use to support their final recommendations. Such clinical guidelines must also have a clear link between the final recommendations and the evidence. Clinical guidelines should ideally be transparent with regards to the methodological strategy used with the support of evidence that helps to produce the final recommendations of their work (173).

In general, it is very much evident that all the included clinical guidelines, except for one, failed to perform well in regards to 'stakeholder involvement' and 'rigour of development' domains (169). The primary focus of these domains is based on the methodological part of guideline development. The results or findings of these domains require correct attention from guideline developers, as the gathering of evidence, along with meticulous interpretation means that the accuracy and quality of each included study must be assessed and appraised individually, step by step. This is vital and necessary, as it is unsatisfactory to assess based only on the study design (i.e. meta-analyses or RCT) to be high rated evidence, as such studies can themselves have sources of bias or methodological issues. Furthermore, some clinical guidelines have linked or connected similar recommendations to a broader or even completely different body of evidence. In the same way, although some of the clinical guidelines made use of grading systems to evaluate the evidence's strength or quality, all the appraisal guidelines barring one did not evaluate or analyse the individual quality or strength of the studies (169).

In the fourth domain, 'clarity of presentation', four of the included guidelines score poorly, as they failed to present the recommendations in a clear format; even if the underlining evidence is unclear, the uncertainty should be highlighted as it is. Furthermore, in the 'applicability domain', almost all the guidelines attained a low score except for one (169). The primary reason for this was due to the methods required for the successful implementation of the clinical guidelines that were not reported clearly and precisely. Also, the detailed and descriptive report

of the barriers, as well as the facilitators and implications of applying the recommendations were missing in the included guidelines. Further, a lack of economic perspective was observed in the evaluated guidelines. This is very much relevant as any clinical decision has implications on benefits, as well as costs to patients, and many other agents such as health suppliers, and society.

The clinical guidelines must include a clear and detailed statement showing that the final recommendations have not been influenced by the interests or views of the funding body, and they must also include a clearly stated description of any sector's contribution to the development of guidelines. Even though the bodies that fund these guidelines are mainly academic institutions and governmental agencies, it was noted by the appraisers that additional details on the purpose and role of these funding bodies or agencies were missing in the content of the guidelines. In order to accomplish the criteria of the AGREE II tool, there needs to be a detailed statement that shows how the interests of the funding body have not influenced or affected the final recommendations. Simultaneously, the authors of all the guidelines should offer a disclosure or report of all competing interests. Nonetheless, as per the reviewers or assessors, this information has not been reported adequately in all the clinical guidelines. This aspect is important, as it is clear that conflicts of interest among guidelines' authors are very common. And the quality of final recommendations may be affected as a result of this. It is therefore important to pay attention to this domain's quality (176).

The second part of the research (Table 3) examined the extent to which the recommendations had been supported by high-quality evidence (i.e. systematic review). The guidelines in our study, of which there were nine, varied in length from four pages to 99 and cited anywhere from five references to 259. The findings from this appraisal were concerning. Across every recommendation reviewed only two were deemed to be sufficiently supported by high-quality evidence. The majority of the guidance documents had conducted a literature review to pinpoint evidence upon which recommendations could be built, however these were narrative literature reviews rather than comprehensive systematic reviews. Meanwhile, only two of the reviewed guidelines included a grading of the certainty or quality of the supporting evidence, and only one of them had clearly linked the recommendation to the body of evidence.

In addition, most guidelines did not include evidence that included children with SHCNs. It should not be implied that recommendations ought to not be made when there is no high-quality evidence relevant to the population of interest. However, the applicability of evidence extrapolated from other populations/settings should be discussed. This transparency for any extrapolation of evidence is vital, particularly for end-users of clinical practice guidelines implementing recommendations labelled as "evidence-based" (171).

To conclude, we discovered that very few guidelines had a clear link between evidence and final recommendation and very few applied clear grades to demonstrate the quality of evidence referred to. When rendering evidence-based recommendations more open, it would be advisable for evidence-rating frameworks to be more broadly applied (such as the GRADE system) (176). This would need to go further than simply measuring the validity of the supporting evidence but also take into account the clinical relevance of certain evidence in the given situation. A detailed provision of the strengths and limitations of the evidence underpinning recommendations will thus enable clinicians to tailor the way recommendations are applied to their patients. Accordingly, the quality of research, the consistency of findings, the lack of ambiguity in the evidence, and the suitability of research design must be all taken into careful account (171).

In general, the most recent guidelines (169) received higher AGREE II scores as compared to the other guidelines, which might indicate an improvement in the development of guidelines over the time period. This improvement should be applauded and encouraged, especially when a large organisation, such as the American Academy of Paediatric Dentistry (AAPD), acknowledges the importance of adhering to the recommendations of the Appraisal of Guidelines Research and Evaluation (AGREE) and other standards to improve the overall quality of clinical guidelines. These changes in reporting and development of guidelines should be continued and this exemplary works should be followed by all developers for any future work.

The quality of clinical guidelines has been defined as 'the confidence that the potential biases of guideline development have been addressed adequately and that the recommendations are both internally and externally valid, and are feasible for practice' (81). The ratings of the assessors indicate that many of the guidelines and recommendations on oral health care for

children with SHCNs have significant shortcomings, as assessed by the AGREE II tool. This can be best illustrated by the fact that all but one of the included (clinical) guidelines were recommended by the three assessors except for one guideline (169).

This study aimed to present a closer analysis of the existing state of the clinical guidelines in this specific area, which considers children with SHCNs and determines how much attention is provided to this particular group in the area of oral health care and dental treatment. The quality and reporting of the included guidelines for children with SHCNs in paediatric dentistry are very poor. Despite the existing number of guidelines and recommendations for children with SHCNs in dentistry, the current situation is not acceptable. The scientific community must come together to ensure that all children with SHCNs are treated optimally and equally.

As a next step in this thesis, we planned to assess the effects of different interventions to increase the acceptance of LA, a common treatment requirement in dental care for children and adolescents with and without special healthcare needs. In many areas of healthcare, the evidence base is insufficient to make recommendations, and conduction a systematic review might help with identifying a potential evidence for children with SHCNs. A deep understanding of availability of evidence in this area seems appropriate to ultimately help to secure a greater comprehension of children's care needs and the present clinical recommendations and evidence with regard to children with SHCNs.

3.7 Summary

The development and content of clinical guidelines in the area are concerning in terms of the low score attributed to the majority of the most domains. Therefore, the scientific community must recognise the urgent need to enhance the quality and strength of the existing clinical guidelines on oral health care for children with SHCNs in the field of paediatric dentistry by the use, as well as the implementation of current Clinical Practice Guideline reporting standards.

CHAPTER FOUR

Interventions for increasing acceptance of local anaesthetic in children and adolescents having dental treatment

4.1 Abstract

Background

Delivery of pain-free dentistry is crucial for reducing fear and anxiety, completion of treatment, and increasing acceptance of future dental treatment in children. Local anaesthetic (LA) facilitates this pain-free approach, but it's use remains challenging. A number of interventions to help children cope with the delivery of LA have been described, with no consensus on the best method to increase its acceptance.

Objectives

To evaluate the effects of methods for acceptance of LA in children and adolescents during dental treatment.

Search methods

Cochrane Oral Health's Information Specialist searched the Cochrane Oral Health's Trials Register (to 24 May 2019); the Cochrane Central Register of Controlled Trials (CENTRAL; 2019 Issue 4) in the Cochrane Library (searched 24 May 2019); MEDLINE Ovid (1946 to 24 of May 2019); Embase Ovid (1980 to 24 May 2019); and Web of Science (1900 to 24 May 2019). The US National Institutes of Health Ongoing Trials Register (ClinicalTrials.gov) and World Health Organization International Clinical Trials Registry Platform were also searched to 24 May 2019. There were no restrictions on language or date of publications.

Selection criteria

Parallel randomised controlled trials (RCTs) of interventions used to increase acceptance of dental LA in children and adolescents under the age of 18 years.

Data collection and analysis

We used standard methodological procedures expected by Cochrane. We performed data extraction and assessment of risk of bias independently and in duplicate. We contacted authors for missing information. We assessed the certainty of the body of evidence using GRADE.

Main results

We included 26 trials with 2435 randomised participants aged between 2 and 16 years. Studies were carried out between 2002 and 2019 in dental clinics in the UK, USA, the Netherlands, Iran, India, France, Egypt, Saudi Arabia, Syria, Mexico, and Korea. Studies included equipment interventions (using several LA delivery devices for injection or audiovisual aids used immediately prior to or during LA delivery or both) and dentist interventions (psychological behaviour interventions delivered in advance of LA (video modelling), or immediately prior to or during delivery of LA or both (hypnosis, counter-stimulation).

We judged one study to be at low risk and the rest at high risk of bias. Clinical heterogeneity of the included studies rendered it impossible to pool data into meta-analyses. None of the studies reported on our primary outcome of acceptance of LA. No studies reported on the following secondary outcomes: completion of dental treatment, successful LA/painless treatment, patient satisfaction, parent satisfaction, and adverse events. No studies included children with SHCNs.

Audiovisual distraction compared to conventional treatment

The evidence was uncertain for the outcome pain-related behaviour during delivery of LA with a reduction in negative behaviour when 3D video glasses were used in the audiovisual distraction group (risk ratio (RR) 0.13, 95% confidence interval (CI) 0.03 to 0.50; 1 trial, 60 participants; very low-certainty evidence).

The wand versus conventional treatment

The evidence was uncertain regarding the effect of the wand on pain-related behaviour during delivery of LA. Four studies reported a benefit in using the wand while the remaining studies results suggested no difference between the two methods of delivering LA (six trials, 704 participants; very low-certainty evidence).

Counter-stimulation/distraction versus conventional treatment

The evidence was uncertain for the outcome pain experience during delivery of LA with children experiencing less pain when counter-stimulation was used (RR 0.12, 95% CI 0.04 to 0.34; 1 trial, 134 participants; very low-certainty evidence).

Hypnosis versus conventional treatment

The evidence was uncertain for the outcome pain experience during delivery of LA with participants in the hypnosis group experiencing less pain (mean difference (MD) -1.79, 95% CI -3.01 to -0.57; 1 trial, 29 participants; very low-certainty evidence).

Other comparisons considered included pre-cooling of the injection site, the wand versus Sleeper One, the use of a camouflage syringe, use of an electrical counter-stimulation device, and video modelling acclimatisation, and had a single study each. The findings from these other comparisons were insufficient to draw any affirmative conclusions about their effectiveness and were considered to be very low-certainty evidence.

Authors' conclusions

We did not find sufficient evidence to draw firm conclusions as to the best interventions to increase acceptance of LA in children due to variation in methodology and nature/timing of outcome measures. We recommend further parallel RCTs, reported in line with the CONSORT Statement. Care should be taken when choosing outcome measures.

4.2 Background

Description of the condition

Dental caries remains a serious problem in children, affecting 23.3% of five-year olds in England and 27.9% of two- to five-year olds in the USA (177,178). If untreated, caries may lead to pain, infection, malnutrition, and disturbed growth (179,180). Social and financial consequences may include days off school or work, referral to specialised care and general anaesthetic resulting in increased costs (181). Surgical approaches and new preventive strategies have been developed and widely researched (182,183). Once dentinal caries is established, restorative or surgical treatment is needed, traditionally requiring local anaesthetic (LA).

Dental anxiety is a well-known barrier to treatment, commonly developing during childhood or adolescence (184). Early onset of dental anxiety may have significant consequences, being associated with behavioural problems that may lead to increased pain perception and interference with the treatment provided (185–187). Ultimately, children's dental anxiety may lead to avoidance of treatment and irregular attendance in adulthood (188).

The aetiology of dental anxiety is multifactorial. Children's cognitive abilities, parental anxiety and previous negative dental or medical experiences seem to play a crucial role in the development of dental anxiety (189,190). Invasive procedures, injections and drilling in particular, appear to be the most anxiety-inducing treatments in children (191).

Dental injection phobia is a subtype of blood-injury-injection phobia. Milgrom considers general fear of injections, including pain and fear of injury, to be the main aspects of dental injection fear (192). In children, needle phobia was found to be significant, with a prevalence of 19% in four- to six-year-olds. Fear of needles seems to decrease with age, possibly due to cognitive maturation or development of coping behaviours (191). Nevertheless, prevalences of 11% of 10- to 11-year olds and 11% of 18-year olds shows the significant importance of fear of intraoral injections (191,193). Furthermore, authors have found a strong relationship between blood-injury-injection phobia and dental anxiety (193). Additionally, dental anxiety and pain of injection seem to be strongly correlated, with highly anxious patients reporting increased pain perception and duration (187). Weisman showed that inadequate analgesia for invasive medical procedures in young children may reduce the effect of appropriate analgesia

in the future (194). Similarly, it appears that previous experiences with dental injections may lead to behavioural problems in subsequent treatment sessions (195).

Delivery of pain-free dentistry is crucial for reducing fear and anxiety, facilitating delivery of treatment, developing a trusting dentist/patient relationship, and accepting future treatment. Delivery of LA is a vital part of this; however, it remains one of the most challenging aspects of paediatric dentistry.

Description of the intervention

Delivery of high-quality dentistry to children is closely linked to a non-threatening approach and pain-free treatment. A number of behaviour management techniques have been proposed and are consistently applied during treatment, in order to achieve successful outcomes (196–198). Delivery and acceptance of dental LA is one of the most trying aspects of treatment. In order to facilitate this, several specific techniques and materials have been developed and researched. This Cochrane Review focused on interventions specifically used for delivery of LA. The use of other behaviour management techniques is implied during all steps of dental treatment. Although these may indirectly influence acceptance of LA, they were not specifically discussed in this review.

In general terms, interventions were considered successful when treatment was completed, or anxiety and pain reduced in comparison to control groups. These interventions are aimed at increasing acceptance of LA, often with completion of the proposed dental treatment as an end result. In other studies, authors undertook assessments of children's pain and anxiety by using physiological assessment questionnaires or interviews, anxiety scales, and behavioural assessment (199,200).

Meechan described three factors that influence discomfort during delivery of LA: factors related to the patient, equipment factors, and aspects that are under control of the dentist (201).

Patient factors

As previously discussed, dental anxiety seems to have a multifactorial aetiology, being closely related to child psychological factors (202). The level of generalised anxiety and psychological function seem to be determinant factors in children's dental anxiety (195,203). This may, in turn, influence children's acceptance of dental treatment, including delivery of LA.

Equipment factors

Equipment factors include interventions delivered immediately prior to and during LA as well as LA delivery devices (where the intervention is injection) and materials, such as topical LA.

The use of visual or auditory technology has been suggested as a distraction technique in order to reduce anxiety and pain perception during delivery of dental treatment (including LA) for children.

Aitken 2002; Baghdadi 2000a; Marwah 2005; and Prabhakar 2007 studied the effect of music distraction on anxiety, pain, or behaviour for children undergoing dental treatment with LA (204–207). Similarly, the use of videos either prior to or during treatment (including audiovisual glasses) has been studied as a possible distraction technique by Hoge 2012; Ingersoll 1984; Melamed 1975a; and Ram 2010 (208–211). These were used independently or in conjunction with pharmacological behaviour management techniques.

Although topical anaesthetic is commonly used, controversy remains on its efficacy in reducing pain of dental injections in children (212–218). Similarly, Aminabadi 2009a studied the effect of pre-cooling the injection site, followed by topical anaesthetic, for delivery of LA. The gauge or length of the needle (219,220) and the temperature of the cartridge (221). have equally been investigated for their influence on pain perception and anxiety of children during delivery of LA.

In recent years, several electronic delivery devices for LA have been developed, that promote distraction by vibration, needleless injections, or transcutaneous electrical nerve stimulation.

The influence of electronic devices for infiltration or intraligamental anaesthesia on children's anxiety and pain has been investigated by a number of authors (190,222–230). Sixou 2008 studied treatment success rates following LA with an electronic device for intraosseous LA (231). In 2009, the same author assessed children's pain perception using this device (200). Roeber evaluated the effects of using a vibrating attachment to the syringe for LA in children (232). Arapostathis compared acceptance, preference and efficacy of a needleless injection device to conventional syringes in children (233). Similarly, transcutaneous nerve stimulation was studied as an alternative to conventional LA in children (234–236).

Dentist factors

Non-pharmacological interventions

Non-pharmacological interventions have been suggested in order to increase acceptance of LA. These methods may include verbal distraction by the dentist, the use of non-threatening words (or 'childrenese') to describe dental injections (237), imagery suggestion, systematic desensitisation, or counter-stimulation during LA. These interventions may be delivered in advance of LA or immediately prior to and during LA.

A number of case reports and review articles have focused on systematic desensitisation for dental treatment in children. Several randomised controlled trials have been undertaken in adults but there is a paucity of studies in children (238). A distraction technique involving repeated breathing in and blowing out air was studied as an alternative distraction for children receiving dental LA (239). The same author studied the benefits of imagery suggestion during delivery of LA for children's dental treatment. This technique involves selection of a pleasant image in which the child is asked to concentrate during treatment (199).Other authors studied the influence of counter-stimulation and distraction on pain perception of children during delivery of LA (240).

Hypnosis has been used and researched for delivery of treatment and LA (241,242). Viewing/hiding the needle prior to injection has also been subject of research (243). Several authors found that the time taken to deliver LA has an influence on injection pain (244,245). Similarly, the site of injection may influence pain perception and anxiety, hence certain authors suggesting adoption of treatment sequences that contemplate these parameters (246).

Pharmacological interventions

Ultimately, pharmacological techniques such as inhalation, oral, intranasal or intravenous sedation have been widely used as adjuvants to delivery and acceptance of LA. A recent Cochrane Review investigated the efficacy of conscious sedation for paediatric dental treatment (197). The authors found weak and very weak evidence supporting the effectiveness of oral midazolam and nitrous oxide, respectively.

Pharmacological interventions were not the focus of this review and for that reason studies where sedation was used to increase acceptance of LA were not included. The inclusion criteria

included studies where standardised sedation was equally used in all arms of the studies (except if sedation was the intervention).

How the intervention might work

Provision of pain and anxiety-free LA is of utmost importance. A number of interventions to help children cope with delivery of LA have been discussed in the literature.

A common aim of interventions is to reduce pain and anxiety during injection. Some pre-treatment reviews have shown that children need time to rehearse their coping strategies. Other interventions are given just prior to the injection and others are given just prior to, during the injection, and continue onwards during the dental treatment.

Equipment factors may work differently in order to reduce anxiety and enable LA delivery: music and audiovisual technologies aim to redirect the child's attention away from the procedure. Furthermore, it has been suggested that music provides comfort and induces relaxation at a neurological level (247). The use of topical anaesthetic, the influence of the gauge of the needle, site/order of injection and time taken to deliver LA are all factors that have implications on pain perception during injection (201). One may argue that an additional benefit of topical anaesthetic may be reassurance of using an anaesthetic agent prior to injection. The use of electronic injection devices, similarly, may influence pain perception during delivery of LA. These devices may also benefit from a different appearance to traditional syringes, possibly increasing children's acceptance (224). Clinician's factors as counter-stimulation, breathing techniques or imagery suggestion may act as distraction methods. The latter two also aim to induce relaxation (199). Similarly, systematic desensitisation aims to promote a relaxed state, while exposing children to fear-inducing stimuli (238). Finally hypnosis will work very similarly by redirecting children's attention away from the procedure while influencing their feelings, perception, and behaviour (248).

The type of surgical procedure may be a factor influencing the overall anxiety of the child, including during LA delivery.

Short-term benefits of successful interventions include successful delivery of LA and completion of dental treatment. This would occur at the current or at subsequent appointments or both, ultimately leading to restoration of oral health. The long-term benefit may involve

reduction of dental anxiety, leading to acceptance of future treatment and development of positive attitudes towards oral health.

Why it is important to do this review

Local anaesthetic is still required for a number of procedures in paediatric dentistry. There is, however, no consensus on what the best intervention is to increase its acceptance.

Several authors looked at interventions for increasing children's acceptance to invasive medical treatment. One Cochrane Review looked at psychological interventions for non-dental needle-related procedural pain and distress in children and adolescents. This review focused on cognitive techniques, behavioural interventions, and combined (cognitive-behavioural) interventions. The authors concluded that psychological interventions, especially distraction, hypnosis, and combined cognitive-behavioural interventions can be successful (249). Similarly, another Cochrane Review looking at interventions to assist induction of general anaesthesia in children, studied psychological interventions, environmental interventions, equipment modification, social interventions, and anaesthetic communication. The authors felt that non-pharmacological interventions such as acupuncture, clowns/clown doctors, playing videos of the child's choice, low sensory stimulation, and hand-held video games need further investigation in reducing anxiety and improving co-operation (250).

A number of studies and reviews have researched the effect of interventions to reduce preoperative anxiety in adults. Bradt looked at music interventions and concluded that listening to music may have a beneficial effect on preoperative anxiety (247). Adult studies interestingly include alternative therapies as acupuncture for reducing anxiety prior to dental treatment (251).This technique has been researched in children for reduction of gag reflex during impressions for orthodontic treatment, however, the authors are not aware of any published studies on its use for increasing acceptance of LA (252).

To our knowledge, there are no comprehensive systematic reviews on interventions to facilitate delivery of dental LA in children and adolescents. Although certain interventions have shown to be successful, controversy remains regarding a number of techniques, leading to confusion and empiric application in clinical settings.

We felt that reviewing the available evidence would further our understanding of existing techniques, as well as determine whether further research on this topic was warranted.

4.3 Objectives

To evaluate the effects of methods for acceptance of local anaesthetic in children and adolescents during dental treatment.

4.4 Methods

Criteria for considering studies for this review

Types of studies

We included parallel randomised controlled trials. We excluded quasi-randomised and cross-over trials.

Types of participants

Children and adolescents up to 18 years old having dental treatment under local anaesthetic (LA) without general anaesthesia. Studies that included participants over the age of 18 were not included in this review, to ensure our search was limited to children. If studies included both children and participants over 18 years old, they were excluded, unless authors clearly provided separate data for children. Children and adolescents (up to 18 years) with any form of special healthcare needs were included in this review.

Types of interventions

Classification of interventions is complex and often overlapping, as there is no standard definition in the literature. We decided to adapt Meechan's factors for discomfort of LA and included interventions based on studies referred to in our background.

We included studies comparing the use of dental equipment or dentist-led intervention to increase the acceptance of delivery of LA in children and adolescents against delivery of LA using a conventional syringe (usual care), or any other dental equipment or dentist-led intervention.

Meechan's patient's factors (for example: the level of generalised anxiety and psychological function) were excluded, as interventions often require a multidisciplinary and lengthy approach for which the remit likely extends beyond that of acceptance of LA.

Pharmacological techniques such as oral, inhalation, intranasal and intravenous sedation or general anaesthetic have been subject of a number of trials and systematic reviews, including Cochrane Reviews (e.g. Ashley 2018) (197). For this reason, they were not included in our search criteria. However, if sedation was administered to both study and control groups (hence not the researched intervention), these trials were included in our review.

We, therefore, classified the interventions as follows.

- Equipment factors
    - Audiovisual technology
        - Visual
        - Auditory
        - Combined visual and auditory
    - Topical anaesthetic
        - Topical anaesthetic agents
        - Cooling of injection site
    - LA
        - Gauge of needle
        - Temperature of cartridge
    - Electronic devices
        - Infiltration devices
        - Intraosseous devices
        - Intraligamental devices
    - Other
        - Needleless devices
        - Vibration devices
        - Transcutaneous nerve stimulation
- Dentist factors (non-pharmacological interventions)
    - Imagery suggestion
    - Counter-stimulation
    - Systematic desensitisation
    - Hypnosis
    - Others
        - Language - non-threatening words

- Viewing/hiding needle.
- Time taken to deliver LA.
- Site of injection/order of treatment.

Our acceptance criteria included studies with interventions that were undertaken:

- in advance of delivery of LA (such as video modelling);
- immediately before LA (such as hypnosis);
- during LA (such as distraction or vibration devices).

When different LA delivery systems were studied the intervention was the injection itself.

This Cochrane Review did not look at types, dosage, or efficacy of LA. Pharmacological behaviour management techniques such as sedation were excluded as interventions.

Studies that combined two or more interventions (other than pharmacological) were included and considered separately to single intervention trials.

Types of outcome measures

Primary outcomes

- Acceptance of LA (yes/no)

Secondary outcomes

- Completion of dental treatment (yes/no)
- Successful LA/painless treatment (yes/no)
- Self- or observational assessment of intraoperative distress/pain/acceptance of treatment during provision of LA
- Pain on injection (yes/no)
- Pre and postoperative anxiety measures
- Patient satisfaction: measured by questionnaires
- Parent satisfaction: measured by questionnaires
- Adverse events

Assessment of children's pain and anxiety may be undertaken by one or more methods: physiological assessment (physical signs of anxiety: high pulse rate, release of stress

hormones and dry mouth), questionnaires or interviews, anxiety scales (completed by parents or children), and behavioural assessment (direct observation of the child's behaviour or psychological state by researchers).

By including these secondary outcomes, the authors tried to describe the level of discomfort the child expressed prior to and during LA. In secondary and tertiary settings children are often referred after a successful LA, but unable to tolerate further treatment after that. Successful LA enables the operator to complete treatment, for this reason one of the secondary outcomes is completion of dental treatment.

Adverse events related to specific interventions were recorded where appropriate.

Search methods for identification of studies

Electronic searches

Cochrane Oral Health's Information Specialist conducted systematic searches in the following databases for randomised controlled trials (RCTs) and controlled clinical trials without language or publication status restrictions:

- Cochrane Oral Health's Trials Register (to 24 May 2019);
- Cochrane Central Register of Controlled Trials (CENTRAL; 2019 Issue 4) in the Cochrane Library (searched 24 May 2019);
- MEDLINE Ovid (1946 to 24 May 2019);
- Embase Ovid (1980 to 24 May 2019);
- Web of Science (1900 to 24 May 2019).

Subject strategies were modelled on the search strategy designed for MEDLINE Ovid but revised appropriately for each database. Where appropriate, they were combined with subject strategy adaptations of the highly sensitive search strategy designed by Cochrane for identifying RCTs and controlled clinical trials as described in the *Cochrane Handbook for Systematic Reviews of Interventions* Chapter 6 (253). The search of Embase Ovid was linked to an adapted version of the Cochrane Centralised Search Project filter for identifying RCTs in Embase Ovid. The search strategies are presented in full in Appendix 2.

No restrictions were placed on the language or date of publication when searching the electronic databases. Non-English studies were translated and included in the review.

Searching other resources

Cochrane Oral Health's Information Specialist searched the following registries for ongoing/unpublished trials to 24 May 2019 (see Appendix 2):

- the US National Institutes of Health Ongoing Trials Register (ClinicalTrials.gov; www.clinicaltrials.gov);
- the World Health Organization International Clinical Trials Registry Platform (www.who.int/trialsearch).

We contacted specialists in the field for any unpublished data.

We searched the reference lists of included studies and relevant systematic reviews for further studies.

We checked that none of the included studies in this review were retracted due to error or fraud.

We did not perform a separate search for adverse effects of interventions used, we considered adverse effects described in included studies only.

Data collection and analysis

Selection of studies

Two review authors independently, and in duplicate, assessed titles and abstracts and full texts for inclusion in the review. The search was designed to be sensitive and include controlled clinical trials, these were filtered out early in the selection process if they were not randomised. Disagreement was resolved by discussion. The search was designed to be sensitive and include controlled clinical trials, these were filtered out early in the selection process if they were not randomised. Those studies which did not meet the inclusion criteria were recorded in the excluded studies section of the review and the reason for exclusion was noted in the Characteristics of excluded studies table (see Appendix 3).

Data extraction and management

We extracted information relevant to the objectives and outcome measures into a specially designed data extraction form. Any disagreements were resolved by discussion. Journal or authors' names were masked before selection or extraction. All studies meeting the selection

criteria were included. We collected descriptive data were available in addition to those already outlined. These data were used to provide contextual information for the main outcomes thus aiding interpretation of results from this review.

We recorded the following data for each included study in the Characteristics of included studies table (see Appendix 3).

Data collected included.

- Year study started (if not available, year it was published)
- Country where the study was carried out
- Type of intervention
- Who delivered the intervention
- Who delivered LA
- Who assessed the intervention
- How the intervention was assessed
- Treatment provided
- Previous LA for dental treatment
- Previous treatment of participants
- Setting of intervention/treatment
- Age of the participant
- Gender of the participant

Assessment of risk of bias in included studies

Risk of bias was assessed using Cochrane's tool for assessing risk of bias as described in Chapter 8 of the *Cochrane Handbook for Systematic Reviews of Interventions* Version 5.1.0 (67). We assessed included trials on the following domains as at 'low', 'unclear', or 'high' risk of bias:

- random sequence generation
- allocation concealment
- blinding of participants and personnel
- blinding of outcome assessment
- incomplete outcome data
- selective outcome reporting

- other sources of bias

We reported these assessments for each individual study in the 'Risk of bias' tables. We also presented the results graphically.

Within a study, a summary assessment of low risk of bias was given when there was a low risk of bias for all key domains, unclear risk of bias when there was an unclear risk of bias for one or more key domains, and high risk of bias when there was a high risk of bias for one or more key domains. Across studies, a summary assessment was rated as low risk of bias when most information was from studies at low risk of bias, unclear risk of bias when most information was from studies at low or unclear risk of bias, and high risk of bias when the proportion of information was from studies at high risk of bias sufficient to affect the interpretation of the results.

Measures of treatment effect

For dichotomous outcomes such as acceptance of LA we planned to calculate risk ratios along with 95% confidence intervals. Continuous outcomes such as intraoperative distress was reported as mean and standard deviation, to calculate mean differences and 95% confidence intervals.

Unit of analysis issues

The unit of analysis was the participant. We followed the guidance included in Section 16.1.2 of the *Cochrane Handbook for Systematic Reviews of Interventions* (67). We planned to adjust data derived from cluster-randomised controlled trials to allow for the clustered design. Data from studies with multiple treatment arms were incorporated according to the guidance included in Section 16.5.4 in the *Cochrane Handbook for Systematic Reviews of Interventions* (67).

Dealing with missing data

We followed the advice provided in Section 7.7.3 of the *Cochrane Handbook for Systematic Reviews of Interventions* (67). We contacted study authors to obtain any relevant missing data or discuss data discrepancies. For trials for which we could not obtain missing data, we used the available data from the trial report. We did not use any approaches or methods to account for missing data.

Assessment of heterogeneity

Heterogeneity in the results of the trials was assessed by inspection of a graphical display of the results and by formal tests of heterogeneity. We planned to use a statistical test for heterogeneity (Chi^2) and the I^2 statistic to quantify inconsistency (which describes the percentage total variation across studies that is due to heterogeneity rather than chance, with I^2 greater than 50% considered to show substantial heterogeneity) for each meta-analysis in addition to the pooled estimate and its associated 95% confidence interval (67). Such sources of heterogeneity might include but were not limited to participant characteristics and nature of the interventions. Meta-analysis was considered appropriate when studies were sufficiently similar in terms of clinical and metrological characteristics in conjunction with the Chi^2 test and I^2 statistic.

Assessment of reporting biases

We planned that this was assessed, where appropriate, by inspection of funnel plots of the results and formal tests where sufficient numbers of studies could be pooled for each comparison.

Data synthesis

We planned formal data synthesis in the form of meta-analysis for trials with similar outcome measures, judged to have sufficiently similar experimental procedures and participants. We planned to combine risk ratios (for dichotomous data) and mean differences (for continuous data) using fixed-effect models or using random-effects models if more than three pooled trials.

Subgroup analysis and investigation of heterogeneity

We proposed the following subgroup analyses where data were available.

- Age: subdivided into three groups: under 5, 6 to 11, 12 to 18 years old (as recommended by the British National Formulary when prescribing drugs to children)
- Gender
- Site of LA
- Type of dental procedure

- Pharmacological techniques: subdivided into two groups: pharmacological techniques (as sedation) used on both control and study groups; pharmacological techniques not employed

The proposed subgroups were suggested as they may influence primary or secondary outcomes. Age and cognitive development may influence co-operation and type of intervention applied.

Although it is unclear whether gender will be determinant for acceptance of different types of interventions, it has been referred to in a number of studies as a possible influencing factor.

The type of dental procedure and site of injection may influence completion of treatment, as they may be considered more painful or anxiety inducing. Drilling and more invasive procedures have been considered the most anxiety-inducing treatments (191).

As previously discussed, pharmacological behaviour management techniques were excluded as interventions. Sedation, however, was included as a distinct subgroup if the same technique/agent was equally used on the control and test groups.

Sensitivity analysis

Sensitivity analysis was planned if sufficient numbers of studies were to be included in any meta-analyses to assess the robustness of the results based on the studies result for risk of bias.

Presentation of main results

We developed 'Summary of findings' tables using GRADEpro software (254) for the main comparisons and the following outcomes of this review: acceptance of LA, completion of dental treatment, successful LA/painless treatment, self- or observational assessment of intraoperative distress/pain/acceptance of treatment during provision of LA, patient satisfaction, and adverse events.

We assessed the certainty of the body of evidence with reference to the overall risk of bias of the included studies, the directness of the evidence, the inconsistency of the results, the precision of the estimates, and the risk of publication bias. We categorised the certainty of the body of evidence for each of the outcomes as high, moderate, low or very low.

4.5 Results

4.5.1 Description of studies

Results of the search

Database searching identified 2649 references, with an additional 21 records identified through other sources. Hand searches were continued up to May 2019 and repeated regularly, including email alerts, handsearching on relevant databases and handsearching of articles. After removing duplicates, the number of records was reduced to 1508. These records were screened independently and in duplicate and we discarded all but 83 studies for a full-text assessment. From those records only 26 studies met the inclusion criteria of this review. One study is awaiting classification and seven are ongoing. We present this process as a flow chart in Figure 1.

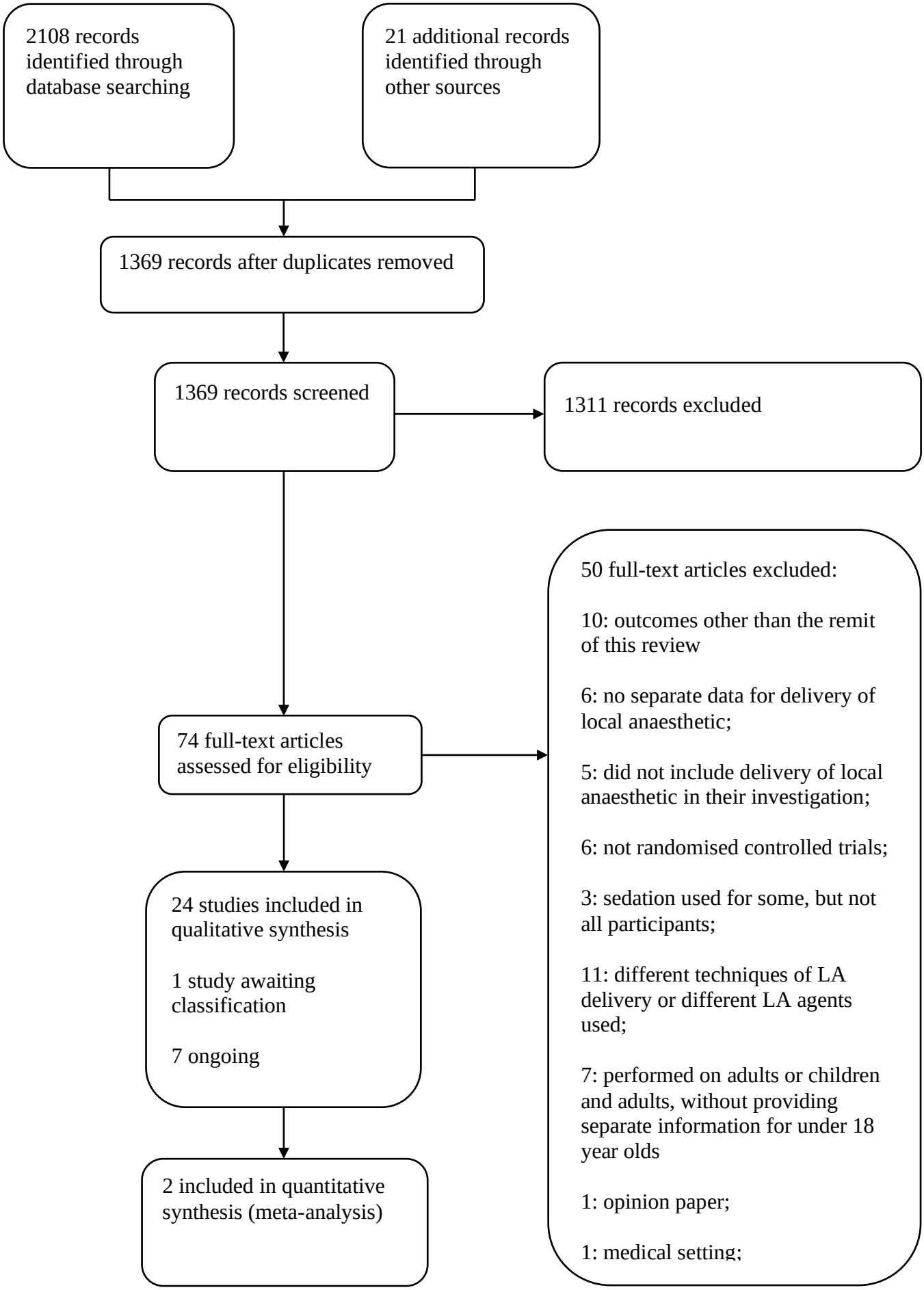


Figure 1: PRISMA flow diagram

Included studies

All 26 included studies were randomised controlled trials with parallel designs (225,228,259–268,229,269–274,240,242,246,255–258). There was substantial clinical heterogeneity across studies in terms of the interventions used, timing, and nature of the outcomes measured.

Characteristics of the participants

We only included studies performed on participants under 18 years old or studies that provided separate data for children. The ages of the children in the included studies ranged from 2 to 16 years. One study did not report the age range of its sample but reported on mean age in each group and only included children below the age of 15 years (268).

The number of children randomised ranged from 20 to 200, with a total number of 2435 of children. All children recruited needed at least one appointment for treatment requiring local anaesthetic (LA).

Characteristics of the trial settings

Four studies were carried out in the UK ((228,255–257), three in the Netherlands (225,229,258), three in Iran (240,246,259), three in the USA (260–262), six in India (263–268), one in France (242), two in Saudi Arabia (269,270), one in Egypt (271), one in Mexico (272), one in Syria (273), and one was carried out in Korea (274).

Characteristics of the interventions

All interventions of the included studies as previously discussed under Types of interventions.

Factors for LA	Type of intervention	Characteristics of the intervention	Studies
Equipment factors			
	Audiovisual technology		
		Visual	We found no eligible studies
		Auditory	Nuvvula 2015
		Combined visual and auditory	Nuvvula 2015, Al-Khotani 2016, Al-Halabi 2018
	Topical anaesthetic		
		Topical anaesthetic agents	We found no eligible studies
		Cooling of injection site	Aminabadi 2009b
	Local anaesthetic		
		Gauge of needle	We found no eligible studies
		Temperature of cartridge	We found no eligible studies
	Electronic devices		

		Infiltration devices	Allen 2002, Asarch 1999, Baghlaf 2015, Gibson 2000, Kandiah 2012, Mittal 2015, Nieuwenhuizen 2013, Tahmassebi 2009, Versloot 2005, Versloot 2008.
		Intraosseous devices	We found no eligible studies
		Intraligamental devices	We found no eligible studies
	Others		
		Needleless devices	We found no eligible studies
		Vibration device	Tung 2018
		Transcutaneous nerve stimulation	We found no eligible studies
		Camouflage syringe	Ujaoney 2013
Dentist factors (non-pharmacological interventions)			
	Imagery suggestion		We found no eligible studies
	Counter stimulation/distraction		Aminabadi 2008, Lee 2013, Kamath 2013, Abdelmoniem 2016, Paryab 2014; Tung 2018
	Systematic desensitisation		We found no eligible studies
	Hypnosis		Huet 2011, Oberoi 2016, Carrasco 2017
	Others		

		Language - non-threatening words	We found no eligible studies
		Viewing/hiding needle	We found no eligible studies
		Time taken to deliver local anaesthetic	We found no eligible studies
		Site of injection/order of treatment	We found no eligible studies
		Video modelling	Paryab 2014, Al-Namankany 2014
		Breathing techniques	Sridhar 2019

Table 6: Characteristics of the interventions

Nine studies compared delivery of LA using a computerised device (the wand) to delivery of LA using conventional syringes (228,229,256–258,260,261,264,275). One study compared delivery of LA using the wand to LA delivery using Sleeper One (225).

Two studies looked at video modelling: Al-Namankany 2014 compared the effect of video modelling showing a dentist delivering LA and performing a restoration compared to a video of the same dentist delivering oral hygiene advice in a non-clinical setting (255). Paryab 2014 compared the behaviour of children who had an acclimatisation visit to that of children who watched a video of an acclimatisation visit (259).

Nuvvula 2015 compared the effect of music (using a MP3 player) and the use of audiovisual glasses to a control group (265). Al-Khotani 2016 compared audiovisual distraction (glasses) to a control group (269). Al-Halabi 2018 compared audiovisual distraction using a VR box and a tablet to a control group (273).

Several authors studied distraction and counter-stimulation: Aminabadi 2008 compared three groups: LA only, distraction and LA, and counter-stimulation, distraction and LA (276). Lee 2013 looked at the effect of pulling the mucosa during delivery of LA, when compared to conventional delivery of LA (without pulling the mucosa) (277). Similarly, Tung 2018 looked at placing manual vibration with the operator's finger adjacent to the injection site, compared to conventional LA. Tung 2018 also looked at using DentalVibe as an electrical vibration device compared to manual vibration and conventional LA (262). Kamath 2013 compared the use of combined breathing exercises to a distraction technique (raising the legs and writing names in the air - WITAUL technique) (263). Sridhar 2019 compared breathing exercises "bubble breath exercise" to conventional delivery of LA (267). Similarly, Abdelmoniem 2016 compared passive distraction, active distraction and passive-active distraction, including leg movements (271).

Aminabadi 2009b looked at the effect of pre-cooling the injection site prior to administration of topical anaesthetic and LA, to conventional delivery of topical anaesthetic and LA only (278).

Huet 2011; Oberoi 2016; and Carrasco 2017 looked at the influence of hypnosis in children's acceptance of LA by comparing children who had hypnosis prior to and during delivery of LA, to children that had delivery of LA without hypnosis (242,266,279).

Ujaoney 2013 compared the use of a syringe camouflaging device to delivery of LA using a conventional syringe (268).

We found no studies where cognitive behaviour therapy was used as an intervention for the purpose of increasing acceptance of LA.

Characteristics of the outcomes

No studies reported on our primary outcome (Types of outcome measures), which was acceptance of LA.

All included studies reported on one of our secondary outcomes: self- or observational assessment of intraoperative distress/pain/acceptance of treatment during provision of LA. Some authors reported on other of our secondary outcomes: pain on injection, pre and postoperative anxiety measures, patient satisfaction or parent satisfaction, however these were often reported in conjunction with the whole dental treatment or appointment, and, for that reason, we were not always able to include the data in our review. The different methods used by authors to assess distress are summarised in Additional Table 2. These included:

- self-reported scales, such as the Wong-Baker FACES® Pain Rating Scale, visual analogue scales (VAS), or more complex anxiety ratings such as the Modified Child Dental Anxiety Scale: faces: MCDAS(f), the Dental Subscale of the Children's Fear Survey Schedule (CFF-DS), and the Abeer Children Dental Anxiety Scale (ACDAS);
- parent-reported scales either using VAS, simple questionnaires, or more complex Parental Emotional Stress Questionnaire (PESQ);
- investigator-rating scales including Venham scales; the Face, Legs, Activity, Cry, Consolability scale; distress scales with different numbers and categories of rating points; and complex scales as the Modified Yale Preoperative Anxiety Scale.

No studies reported on the following secondary outcomes: completion of dental treatment, successful LA/painless treatment, and adverse events.

Excluded studies

We excluded 49 studies from our review. From these, seven studies were performed on adults or children and adults without providing separate information for under 18 year olds; seven evaluated types of anaesthesia; one assessed the physical appearance of dental injectors; one

assessed the efficacy of analgesic buffering with sodium bicarbonate; one used general anaesthesia; eight did not have separate data for delivery of LA; four did not include delivery of LA in their investigation; five were not true randomised controlled trials; three studies used sedation for some, but not all participants; 10 used different techniques of LA delivery or different LA agents; one was an opinion paper; and one was in a medical setting.

4.5.2 Risk of bias in included studies

We based risk of bias judgements on the information reported in the publications. We contacted study authors when information was missing or was unclear. Figure 2 and Figure 3 illustrate the results of the risk of bias assessment. Risk of bias is difficult to quantify as interventions are dependent on the interaction between child and operator. Nevertheless, it is possible to describe, standardise and quantify these interactions in order to reduce bias. Furthermore, completion of treatment might be influenced by factors such as correct LA delivery technique, or by unique features such as teeth hypomineralisation or irreversible pulpitis, which may lead to increased sensitivity and anxiety.

Allocation (selection bias)

Sequence generation

Fourteen studies described adequate methods of sequence generation, and we judged these to be at low risk of bias (225,229,266,267,273,280,242,255,257,258,262–265). The authors described a range of methods including coin toss, lottery, shuffled cards in a box, table of random numbers, or computer randomisation. Eleven studies reported sequence generation as 'randomised' but did not report the method of sequence generation (228,256,279,259–261,268,270,271,276,277). We judged these studies to be at unclear risk of bias for this domain. One study assigned the first participant to each group randomly by the toss of a coin, but every participant after was assigned via alternation, therefore we judged the study to be at high risk of bias (269).

Concealment of allocation

Studies reported allocation concealment poorly, with only five studies fully describing the method of allocation concealment, which was centralised or third-party assignment (228,255,257,265,267). Kandiah 2012 added that an independent investigator received the randomisation data and placed it into envelopes that were only given to the operator when the patient arrived for treatment (257). The envelopes were opened just before delivery of LA (257). Nuvvula 2015 used centralised or third-party assignment (265). Al-Namankany 2014; Sridhar 2019 used sealed and coded envelopes, that were opened sequentially and Tahmassebi 2009 used a list of envelopes that were only opened immediately before LA (228,255,267). We judged these studies to be at low risk of bias for this domain. Two studies (Aminabadi 2009b; Tung 2018) reported allocation concealment but failed to discuss the process, for this reason they were considered at unclear risk of bias (262,280). We judged the remaining 19 studies as at unclear risk of bias for this domain because of insufficient information to enable a judgement to be made, as the authors did not discuss this.

Blinding (performance bias and detection bias)

Blinding of participants and personnel (performance bias)

Blinding of operators was not possible in the majority of studies, depending on the type of intervention - if the operator delivered the intervention or if the intervention was delivered during LA, it might not have been possible to blind the operator. This was true for all but two studies, Al-Namankany 2014 and Paryab 2014, where the intervention was delivered prior to the appointment (255,259). Blinding of participants was successful in three studies (Al-Namankany 2014; Baghlaf 2015; and Kandiah 2012) but only Al-Namankany 2014 blinded participants and the operator appropriately and therefore, this is the only study that has been awarded low risk (255,257,270). Although Allen 2002; Asarch 1999; and Gibson 2000 discussed that they shielded participants from viewing the syringe, they did not discuss if the sound was reduced, eliminated or standardised (256,260,261). Six studies reported that the operator was not blinded (228,257,265,267,268,277) and 17 did not discuss whether the operator was blinded (225,229,266,270,271,276,279–281,242,256,258,260–264).

Blinding of outcome assessment (detection bias)

Two studies blinded outcome assessors to the intervention, and we judged these studies to be at low risk of detection bias (259,266). Similarly, we considered that studies limited to self-

reporting or parental reporting were at low risk of detection bias (255,257,262). Although in Asarch 1999 one outcome was assessed by an investigator, this outcome was not included in this Cochrane Review, and for that reason this study was judged as low risk (260). Three studies either did not blind the assessor (because this was thought to be impossible) or did not discuss blinding, and they were judged as at unclear risk of detection bias (264,269,280). 17 studies were considered high risk bias (225,229,270,271,276,279–281,242,256,258,260–263,266)

Incomplete outcome data (attrition bias)

We considered 16 studies to be at low risk of attrition bias as they described the number of excluded participants (no differential dropout) (Al-Namankany 2014; Huet 2011; Kandiah 2012; Paryab 2014; Sridhar 2019) or the number of participants reported in the analyses was the same as the number randomised(228,242,266,267,271,276,279,280,255,257,259,260,262–265). We judged Gibson 2000; Versloot 2005; and Versloot 2008 to be at unclear risk as only a percentage of the observations could be included in the analysis (229,258,261). The reason for this discrepancy was due to differences in speed of delivery of the different types of LA used – resulting in longer observation times in one of the groups. Al-Halabi 2018; Al-Khotani 2016; Baghlaf 2015; Lee 2013; Nieuwenhuizen 2013; Ujaoney 2013 reported exclusion of participants but no discussion of which groups did the participants belong to prior to exclusion and were considered at high risk of attrition bias (225,268–270,273,277). Allen 2002 excluded two children as their rating in the outcome measures was considered to be infrequent (256). This rating was the highest of the range in the particular scale for anxiety and distress used by the authors hence the study was considered to have high risk bias.

Selective reporting (reporting bias)

We did not have access to trial protocols; therefore, we used the information reported in the methods and results sections of the trial reports to make a judgement on selective reporting. Al-Halabi 2018 and Al-Khotani 2016 did not present descriptive statistics for the number of participants at the start and end of the studies, and we assessed them as at unclear risk of reporting bias (269,273). All the other studies reported all outcome measures described in the methods section, and we assessed these to be at low risk of reporting bias.

Other potential sources of bias

Nieuwenhuizen 2013 reported that six children were found to have high bone density and for that reason it was not possible to deliver intraosseous LA (225). Intraligamental anaesthetic was delivered, however there was no description as to which group these children belonged to, therefore the study was judged as being at high risk of bias for this domain. Al-Halabi 2018; Carrasco 2017; Sridhar 2019 were also assessed as at high risk of other bias (267,273,279). Four studies were rated as unclear risk (229,256,258,261). In these, delivery of LA with the wand took longer than conventional LA. This may have introduced bias, as it has been reported that time taken to deliver LA influences pain during delivery. Furthermore, as the operator was not blinded to the intervention, it is possible that the delivery speeds in each group might have been biased. By the other hand, one may argue that slow delivery of LA is one of the advantages of the wand in comparison to conventional LA, and for that reason the differences in delivery times may be considered as one of the outcomes. Similarly, Asarch 1999 was awarded unclear risk as the wand was used with high speed only (260). Mittal 2015 was considered high risk as time taken to deliver LA was not recorded or not standardised (264). This may have included bias as some authors studying the same intervention report on time taken and others standardise this factor. Oberoi 2016 was considered at high risk as the authors had a wide age range, with no division into groups for analysis (266). Additionally, there was no discussion of patients' ages on each group, nevertheless the authors calculated a statistically significant correlation between age and resistance in the experimental group. All the other studies were judged to have low risk of other bias.

Overall risk of bias

We judged one study to be at low risk of bias for all domains (255). The rest of included studies were judged to be at high risk of bias for at least one domain (Figure 2: Risk of bias summary).

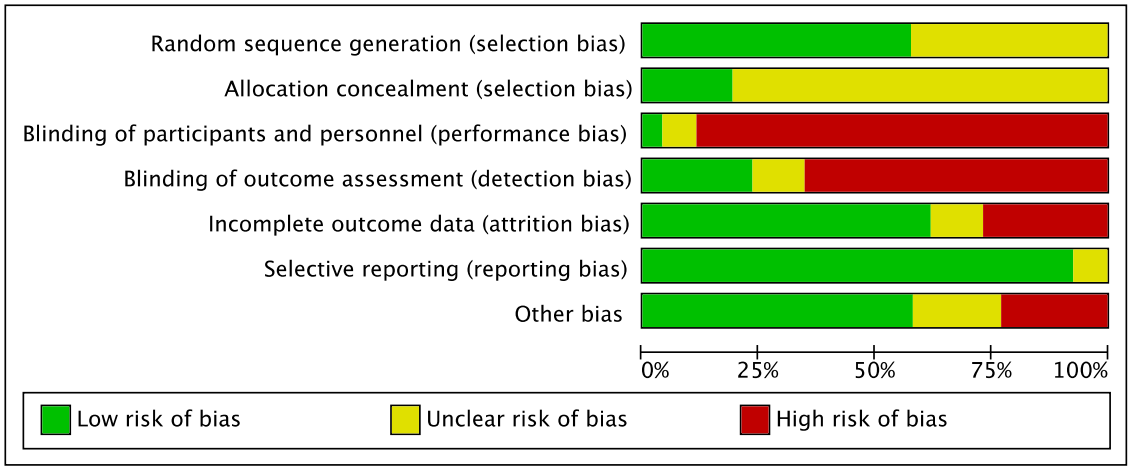


Figure 2: Risk of bias graph

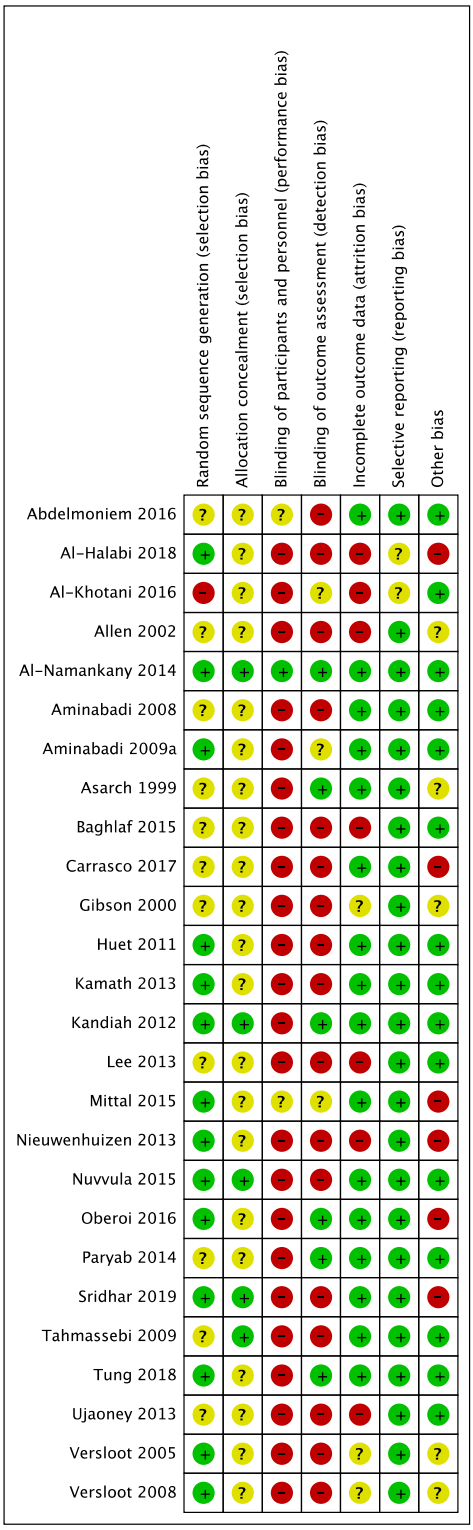


Figure 3:Risk of bias summary for individual studies

4.5.3 Effects of interventions

In order to facilitate understanding of the data, we aggregated the included studies by type of intervention, as described in the Types of interventions section.

- Equipment factors
    - Audiovisual technology (comparison 1)
    - Topical anaesthetic (comparison 2)
    - Electronic delivery systems (comparisons 3 and 4)
    - Other (comparison 5)
- Dentist factors
    - Counter-stimulation (comparisons 6, 7 and 8)
    - Hypnosis (comparison 9)
    - Other (comparisons 10 and 11)

Timing of interventions was as follows:

- Interventions delivered in advance of LA: Paryab 2014 (video modelling, comparison 11) (259).
- Interventions delivered immediately before LA: Al-Namankany 2014 (video modelling, comparison 10) (255); Aminabadi 2009a (pre-cooling injection site, comparison 2) (278); Huet 2011 (hypnosis, comparison 9) (242); Oberoi 2016 (hypnosis, comparison 9) (266); Sridhar 2019 (counter-stimulation, comparison 6) (267).
- Interventions delivered during LA: Abdelmoniem 2016 (counter-stimulation, comparison 6) (271); Al-Halabi 2018 (audiovisual devices, comparison 1) (273); Al-Khotani 2016 (audiovisual devices, comparison 1) (269); Aminabadi 2008 (counter-stimulation, comparisons 6 and 8) (276); Carrasco 2017 (hypnosis, comparison 9) (279); Kamath 2013 (counter-stimulation, comparison 6) (263); Lee 2013 (counter-stimulation, comparison 6) (277); Nuvvula 2015 (audiovisual devices, comparison 1) (265); Tung 2018 (counter-stimulation, comparisons 6 and 7) (262).

- Studies where the injection is the intervention; Asarch 1999; Baghlaf 2015; Gibson 2000; Kandiah 2012; Mittal 2015; Nieuwenhuizen 2013; Tahmassebi 2009; Versloot 2005; and Versloot 2008 (electronic injection devices, comparisons 3 and 4); and Ujaoney 2013 (camouflage syringe, comparison 5) (225,228,270,229,256–258,260,261,264,268).

Comparison 1: audiovisual distraction versus conventional treatment

Three studies, all at high risk of bias, with 248 randomised participants were included in this comparison (265,269,273). Nuvvula 2015 randomised 90 children to one of three groups: music only (group 1), 3D audiovisual glasses (group 2), and conventional treatment (group 3 - control) (265). Al-Khotani 2016 randomised 56 children to an audiovisual distraction group during delivery of LA or to a conventional LA group (269). Al-Halabi 2018 randomised 102 children to one of three groups: audiovisual distraction group using VR box (virtual reality box), audiovisual distraction group using a tablet, and conventional LA group with no distraction (Additional Table 3; Appendix 3) (273). Pooling these studies was not appropriate due to heterogeneity in outcome scales, sites of injection, and timing of assessment of outcomes measures.

Self- or observational assessment of intraoperative distress/pain/acceptance of treatment during provision of LA

Nuvvula 2015 measured behaviour before and during LA administration using the Frankl Behaviour Rating Scale (FBRS) and the Houpt rating scale (265). The authors analysed responses to the Frankl scale as negative versus positive behaviour (defiantly negative or negative versus defiantly positive or positive), and reported behaviour improvement, with fewer children exhibiting negative behaviour during LA in both the music and audiovisual groups when compared to the conventional LA group: risk ratio (RR) 0.31, 95% confidence interval (CI) 0.13 to 0.74, and RR 0.13, 95% CI 0.03 to 0.50, respectively. No improvement was identified when the two distraction methods were compared (RR 0.40, 95% CI 0.08 to 1.90) (Analysis 1.1). On the Houpt scale, the authors presented data in a way that did not allow quantitative assessment. However, the study authors stated that "the ratings on Houpt scale were superior in both the groups of music and audiovisual, compared to the conventional group" (Additional Table 3; Appendix 3) (265).

Al-Halabi 2018 evaluated the effect of audiovisual distraction (VR box and tablet) on behaviour change during inferior alveolar nerve block using the Faces, Legs, Activity, Cry, and Consolability (FLACC) scale (273). When comparing VR box or tablet to the conventional treatment group, the authors reported no difference in behaviour: mean difference (MD) -0.03, 95% CI -1.03 to 0.96, and MD 0.67, 95% CI -0.41 to 1.76, respectively. Additionally, the authors reported no differences between the two audiovisual distraction methods (VR box and tablet) during LA (MD -0.71, 95% CI -1.84 to 0.43) (Analysis 1.2).

Nuvvula 2015 reported on anxiety before and after LA using the Modified Child Dental Anxiety Scale: faces: MCDAS(f) (265). When comparing music alone or audiovisual distraction to the conventional treatment group, Nuvvula 2015 reported lower anxiety MCDAS(f) scores after LA in both distraction groups: MD -6.80, 95% CI -9.82 to -3.78; $P < 0.001$ (music group); and MD -12.60, 95% CI -15.33 to -9.87; $P < 0.001$ (audiovisual distraction) (Analysis 1.5) (265). When comparing the music and audiovisual groups (after LA), the audiovisual group had a significantly lower MCDAS(f) score than the music group: MD -5.80, 95% CI -7.61 to -3.99; $P < 0.001$ (Analysis 1.6).

Al-Khotani 2016 reported on this outcome using self-reported anxiety, measured pre and postoperatively using the Facial Image Scale (FIS) as well as anxiety and co-operation, measured by the modified Venham's scale. In this study, data for FIS and Venham's scale specific to LA were presented graphically only (269). Numeric values were requested from the study authors using the given contact details, with no success. From the given graphs for delivery of LA, there appears to be higher numbers of relaxed children in the intervention group than in the conventional group (just above 50% and below 40%, respectively). Al-Khotani 2016 presented overall data for the LA procedure and reported using the modified Venham's scale that "there was a significant reduction in clinical anxiety throughout the restorative procedure, including injection with local anaesthesia, in the audiovisual distraction group ($P = 0.04$), where this significant reduction was not found in the control group ($P > 0.05$) (265). Additionally, there were no significant differences when using FIS between the audiovisual distraction group and the conventional group ($P = 0.570$) (Additional Table 3; Appendix 3).

Comparison of pulse rates showed an increase in pulse scores before and during treatment for all three groups (music only, audiovisual glasses, and conventional treatment groups) ($P = 0.001$) according to Nuvvula 2015 (265). The two distraction techniques (music group and audiovisual glasses) had a significantly lower mean value in pulse rates during LA when

compared to the conventional group: MD -14.40, 95% CI -19.20 to -9.60 (music group); and MD -9.60, 95% CI -14.62 to -4.58 (audiovisual glasses) (Analysis 1.6). This difference was also significant but less elevated in the music group in comparison with the audiovisual glasses group: MD -4.80, 95% CI -6.87 to -2.73) (Analysis 1.6) (Additional Table 3; Appendix 3).

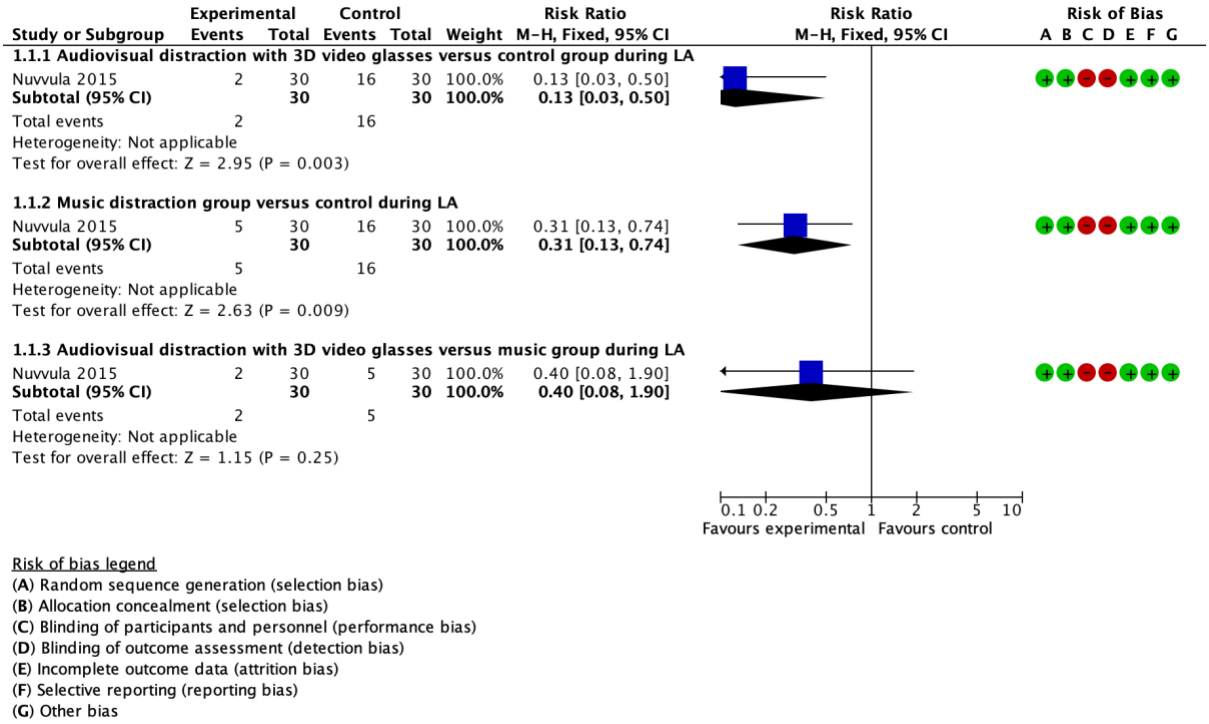
Al-Khotani 2016 reported mean pulse rates and blood pressure after LA and during the whole treatment session (operative procedure) (269). The authors stated that "there were no significant differences in the overall mean pulse rates between the CTR-group [control group] and the AV-group [audiovisual distraction group] (P = 0.564)." There was no difference in blood pressure for participants during the injection period and during the whole procedure (Additional Table 3; Appendix 3). Additionally, Al-Halabi 2018 reported on pulse rates difference when children were still seated on the dental chairs, immediately after inferior alveolar block (273). The authors reported only a significant difference in pulse rates between the audiovisual distraction participants (tablet group only) and the conventional LA group (MD 6.26, 95% CI 2.04 to 10.47). No differences were found between the VR box and the control group or between the VR box and the tablet group: MD 2.88, 95% CI -1.78 to 7.53; and MD -3.38, 95% CI -8.42 to 1.66 (Analysis 1.7).

Pain on injection

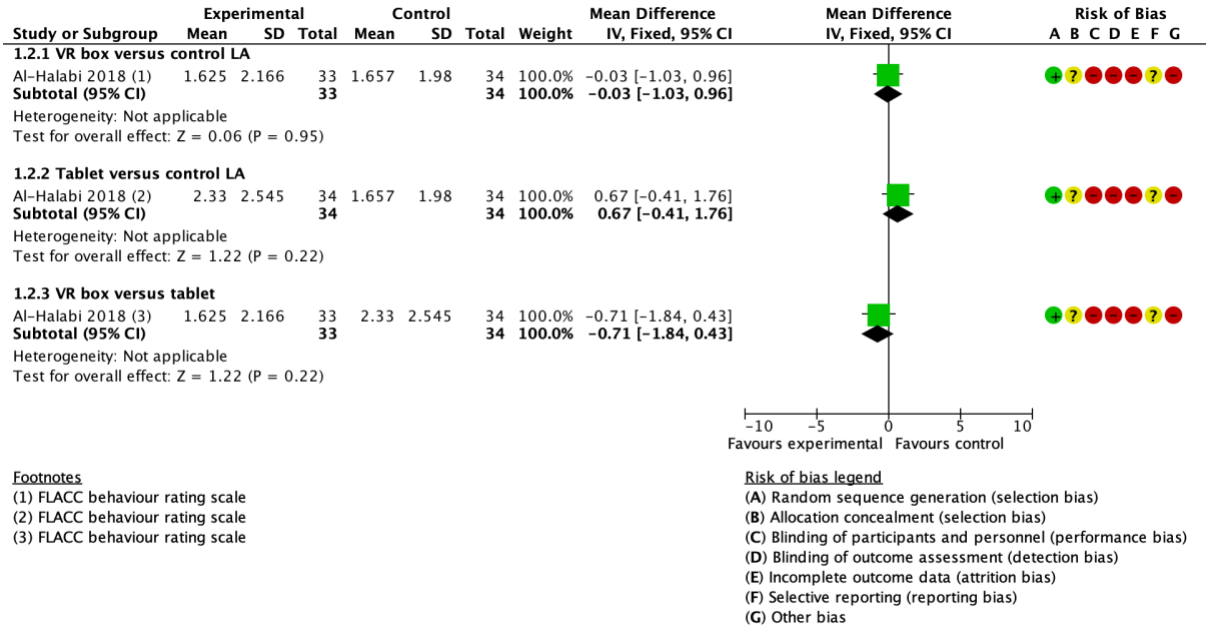
Al-Halabi 2018 measured pain using the Wong-Baker Faces Pain Rating Scale immediately after inferior alveolar block injection (273). When comparing VR box or tablet to the conventional treatment group, Al-Halabi 2018 reported no differences in pain scores after LA in both groups: MD 0.04, 95% CI -0.41 to 0.48 (VR box) and MD 0.22, 95% CI -0.28 to 0.73 (tablet) (273). Also, no difference was reported between the two intervention groups (MD -0.19, 95% CI -0.73 to 0.35) (Analysis 1.3).

Other outcomes

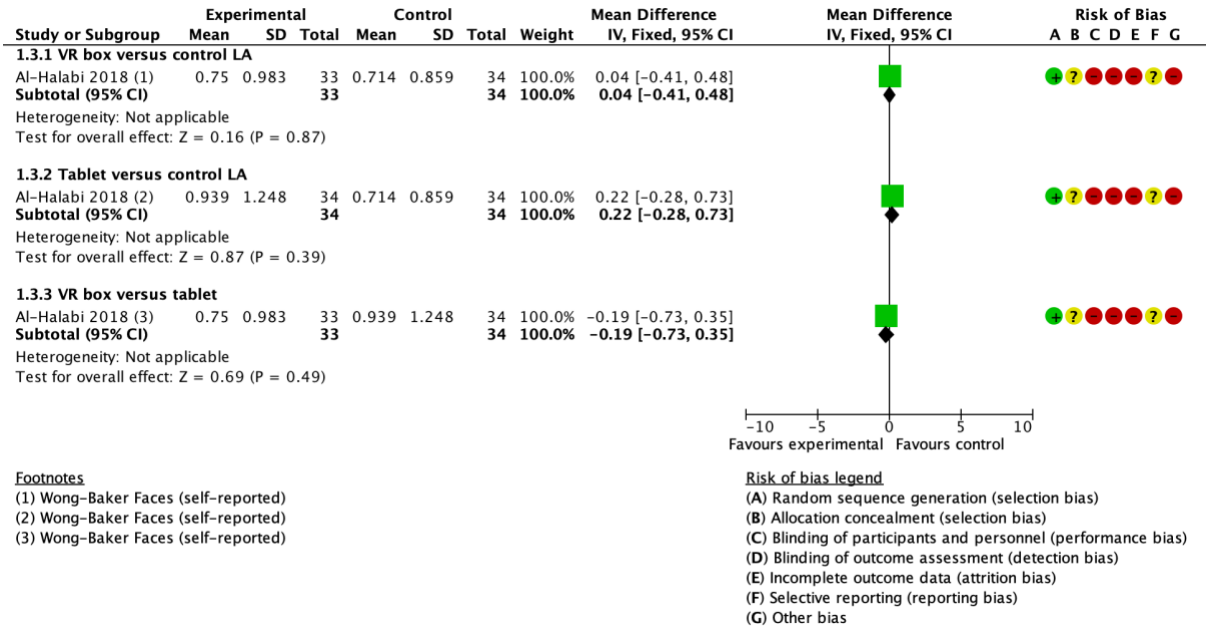
No data on the primary outcome of acceptance of LA, or on any other secondary outcomes including adverse events, were reported.



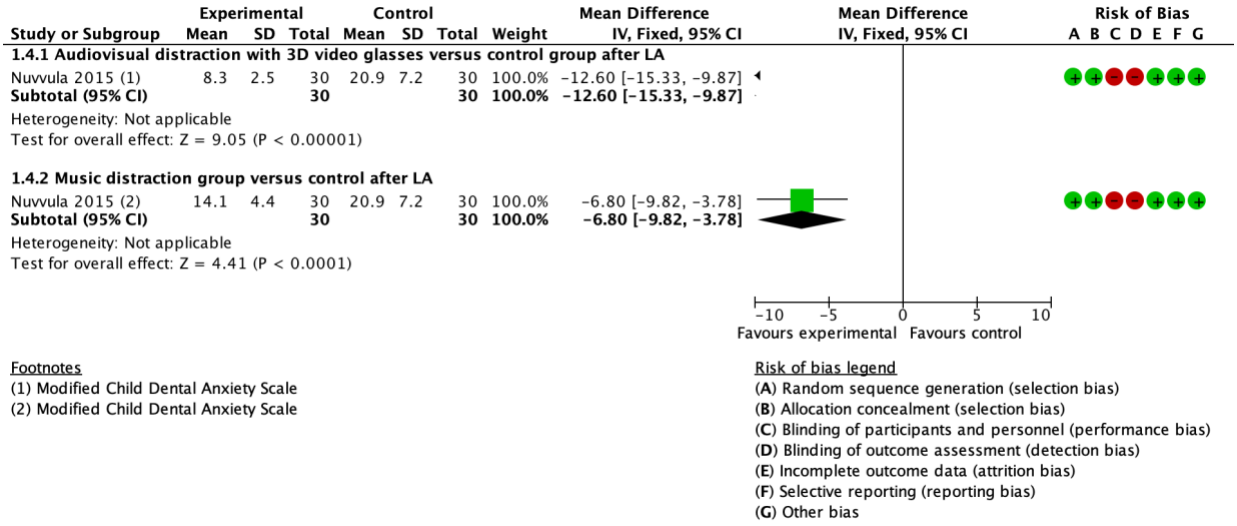
Analysis 1.1.: Audiovisual distraction versus music distraction versus control (Pain-related behaviour - dichotomous (participant with negative behaviour versus participant with positive behaviour)



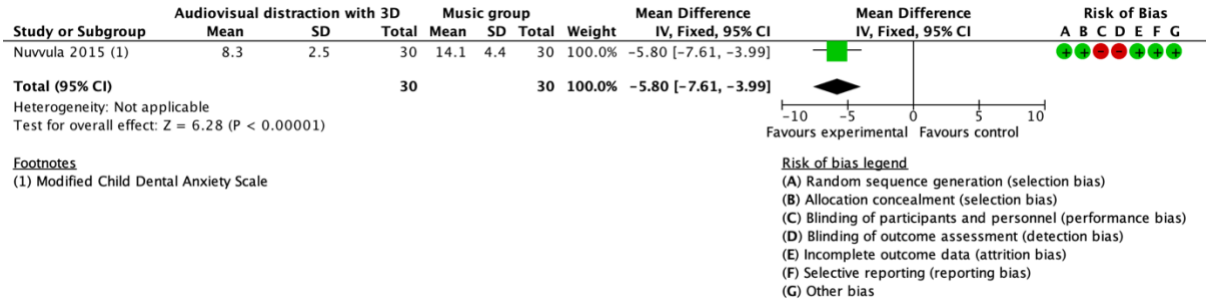
Analysis 1.2.: Pain-related behaviour (FLACC scale 0–10, higher score indicates worst behaviour)



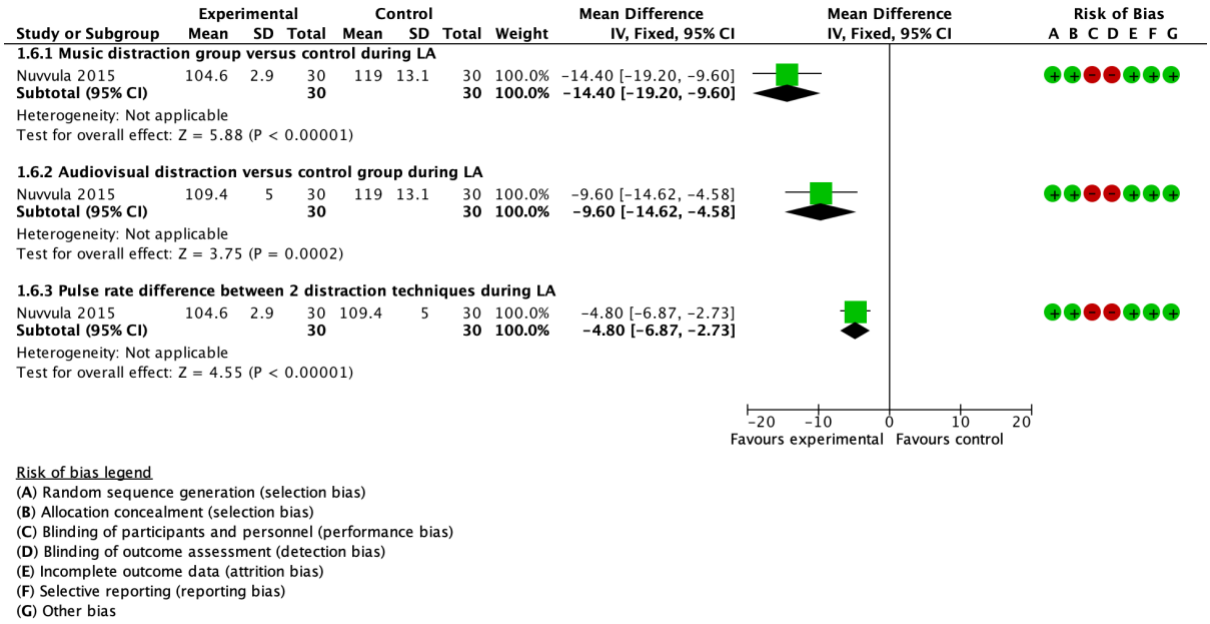
Analysis 1.3.: Pain experience (Wong-Baker Faces score 0-5, higher score indicates worst pain)



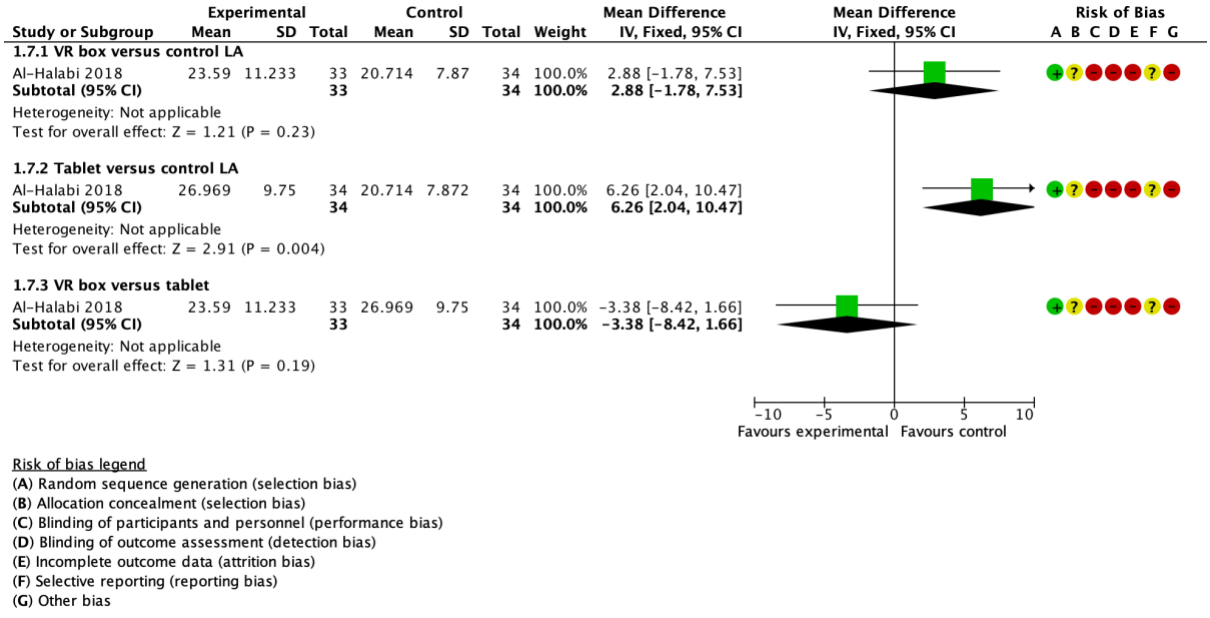
Analysis 1.4.: Anxiety after LA (any distraction vs control) (Modified Child Dental Anxiety Scale score form 5-30, higher scores indicate higher anxiety)



Analysis 1.5: Anxiety between distraction techniques after LA (Modified Child Dental Anxiety Scale score form 5-30, higher scores indicate higher anxiety)



Analysis 1.6.: Pulse rate during LA (any distractions versus control)



Analysis 1.7.: Pulse rate before and after LA

Comparison 2: pre-cooling of the injection site versus conventional treatment

A single study, at high risk of bias, randomised 160 participants to receive either pre-cooling or conventional treatment (280).

Self- or observational assessment of intraoperative distress/pain/acceptance of treatment during provision of LA

Aminabadi 2009a presented data on pain perception/pain experience (distress) using the SEM scale (Sound, Eyes, and Motor scale) in a way that does not allow for further analysis (280). The study authors state that there was statistically significant difference between groups. The authors conclude that pre-cooling reduced pain perception for delivering inferior alveolar nerve block injection (Additional Table 4; Appendix 3).

Other outcomes

No data on the primary outcome of acceptance of LA, or on any other secondary outcomes including adverse events, were reported (Additional Table 14; Appendix 3).

Comparison 3: the wand versus traditional LA

Nine trials with 704 randomised participants compared the delivery of LA using the wand with conventional LA (190,228,229,256,257,260,261,264,270) (Additional Table 5; Appendix 3). All studies were at high risk of bias. Pooling studies was not appropriate due to heterogeneity in outcome scales, sites of injection, and time of outcome measures except for two studies (228,257).

Self- or observational assessment of intraoperative distress/pain/acceptance of treatment during provision of LA

Six studies reported on pain-related behaviour during the injection period for children between the ages of 2 and 11 years old (229,256,258,260,261,270). Pain-related behaviour outcomes were measured as four or five-category scales of distress. Only three of the six trials provided data in a format suitable for inclusion in a meta-analysis (256,258,270). Pooling was not undertaken due to between-study heterogeneity as different distress scales were used at different time intervals for injections at different sites (Additional Table 2; Appendix 3).

Two studies analysing 101 children, reported a reduction of disruptive behaviour, reaction or body movement during the injection period when the wand was used to deliver LA (256,270). Allen 2002 reported that the mean number of 15-second intervals with restraints was significantly fewer during the injection period for the wand group (palatal-anterior and middle-superior nerve or anterior-superior alveolar nerve) compared to the conventional injection, at both buccal and palatal sites (MD -0.85, 95% CI -1.66 to -0.04; P = 0.04; 40 participants) (Analysis 2.1) (256). Baghlaf 2015, with two groups (conventional LA (ID block) and ID block with the wand) reported that disruptive behaviour was reduced in the group that used the wand compared to the conventional LA group (inferior alveolar nerve block group) (MD -0.37, 95% CI -0.71 to -0.02; P = 0.0427; 61 participants) (Analysis 2.1) (270). However, there was inconclusive evidence from the remaining study, with results suggesting either an increase or decrease in the outcome (MD -0.11, 95% CI -0.46 to 0.24; P = 0.55, 140 participants) (Analysis 2.1) (258).

Baghlaf 2015 reported on the effects of intraligamental injection using the wand, however, as there was no comparison group at the same site using traditional LA we were unable to evaluate these effects (Additional Table 5; Appendix 3) (270). The authors reported that children in the intraligamental group with the wand had the least disruptive behaviour during the injection period when compared to other groups (P < 0.001) (Additional Table 5; Appendix 3).

Three studies did not provide numeric data in a suitable format for analysis, and are, therefore, presented as narrative results (229,260,261). Gibson only stated the percentage of patients with disruptive behaviour and failed to report the mean increment and standard deviation by study group, discussing only that "significantly fewer patients cried or exhibited body movements during the first interval of the wand injection than patients given the traditional palatal injection (P< 0.05)" (Additional Table 5; Appendix 3) (261). Versloot 2005 reported on the frequency of pain-related behaviour as a percentage but failed to report on the mean increment and standard deviation for each group (229). Versloot reported less body movement, muscle tension and verbal protest in the first two 15-second intervals in the wand group, before dividing the groups according to their anxiety level (Additional Table 5; Appendix 3) (229). Asarch 1999 did not report on the mean or standard deviation of the study groups, but stated that there were no differences between the wand and the conventional LA groups during the injection period in pain-related behaviour outcomes (F = 1.18, P = 0.31, n = 128) (Additional Table 5; Appendix 3) (256).

Pain on injection

Six studies, with 596 randomised participants and all at high risk of bias, provided data on pain perception, pain experience, or pain rating during the injection period when comparing the wand to conventional LA (229,256,258,260,261,270). Visual Analogue Scales (VAS, including modified versions), SEM scale, and the Wong-Baker Faces Pain Rating Scale were used to measure pain in these trials. Pooling data from these trials was not appropriate due between-study heterogeneity as different scales were used at different times with different sites of injection (Additional Table 2; Appendix 3).

Baghlaf 2015 reported that pain perceptions were significantly higher in the traditional inferior alveolar nerve block group in comparison to the wand group at the same site on injection (MD -0.52, 95% CI -0.60 to -0.44; P < 0.001, 61 participants) (Analysis 2.2) (270). However, there was inconclusive evidence from the remaining studies to suggest a benefit in using the wand to reduce pain during the injection period (229,258,264). Versloot 2005 and 2008, reported no difference in pain scoring (self-reported) when using the wand to deliver LA (MD 0.64, 95% CI -0.69 to 1.97; P = 0.33, 109 participants) or conventional LA (MD 0.49, 95% CI -0.55 to 1.53; P = 0.35, 140 participants) respectively, during the injection period (Analysis 2.2) (260, 247). In addition, Mittal 2015 reported no difference in pain experience when using the wand for buccal infiltration (MD -0.08, 95% CI -0.41 to 0.26; P = 0.64, 100 participants) (229). However, the wand was found to be beneficial in reducing pain perception at buccal sites according to Mittal 2015 findings, using a SEM scale (MD -0.56, 95% CI -0.97 to –0.15; P < 0.001, 100 participants) (229). In addition, at the palatal site, Mittal reported significantly lower pain experience and lower pain perception in the wand group compared to conventional LA: MD -0.56, 95% CI -1.06 to -0.05; P = 0.03, 100 participants, and MD -0.72, 95% CI -1.23 to –0.21; P < 0.001, 100 participants, respectively (Analysis 2.2; Analysis 2.4) (229).

Baghlaf 2015 additionally reported on the effects of the wand at the intraligamental site of injection but because there was no comparison group at the same site using conventional LA, we were not able to include it (Additional Table 5; Appendix 3) (266). Baghlaf reported that children in the intraligamental group with the wand had the least pain perception during the injection period than any other groups (P < 0.001) (Additional Table 5; Appendix 3) (266).

A further two studies, looked at children's pain-related behaviour during delivery of LA but we were not able to include them in a meta-analysis as they failed to report on the standard

deviation of the groups (260,261). Both trials used a 10-point VAS and reported no difference in pain perception or pain rating when using the wand in delivering LA (260,261). Gibson 2000 reported that average pain rating was 3.4 for the wand group and 4.9, 2.7 for the traditional palatal and buccal groups respectively (P < 0.10) (257). Asarch 1999 reported also that the average pain rating for the wand group was 4.5 while it was 3.6 for the conventional groups (F = 1.18, P = 0.31, n = 128) (Additional Table 2; Appendix 3) (256).

Two studies, all at high risk of bias, with 68 analysed participants between the ages of 4 and 13 years of age, compared the patient-reported pain for the overall period of injection using the wand and conventional LA (228,257). Pain perception was initially measured using a modified VAS with anchors of zero and 100%. The VAS scores were subsequently divided into categories of no pain (< 20%), mild (20% to 40%), moderate (40% to 60%), severe (60% to 80%), and intolerable pain (> 80%) (Additional Table 5; Appendix 3). When categorical data were analysed as no pain versus any category of pain, the pooled estimate was compatible with either an increase or decrease in the proportion of children experiencing pain with the wand (RR 1.15, 95% CI 0.83 to 1.59, P = 0.40) (Analysis 2.3). A similar result was observed when the categorical data were analysed as absence of pain or mild pain versus moderate, severe or intolerable pain (RR 1.12, 95% CI 0.85 to 1.47, P = 0.42) (Analysis 2.3).

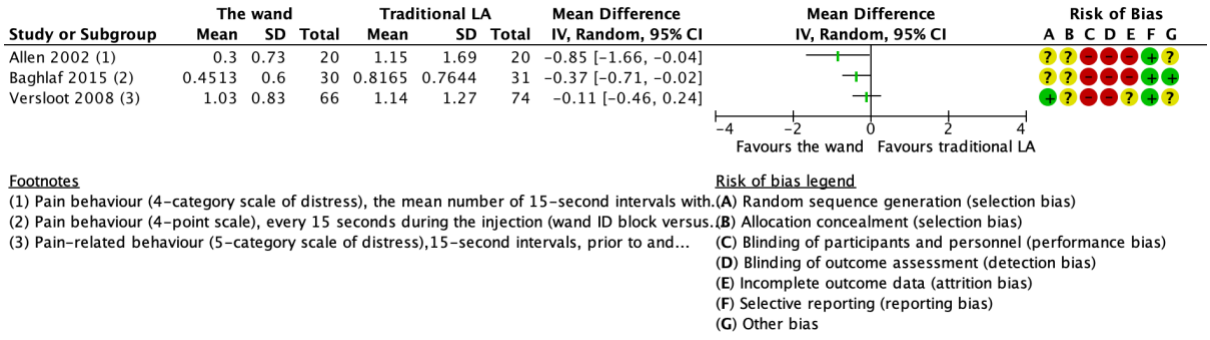
Pre and postoperative anxiety measures

Three studies with 315 randomised participants and all at high risk of bias, reported on anxiety during the injection period when comparing the wand with traditional LA (228, 260, 247).Venham's Anxiety Scale (including modified versions) was used in these trials. Pooling these trials was not appropriate due to the wide variety of measures used and at different time points or intervals during the injection period.

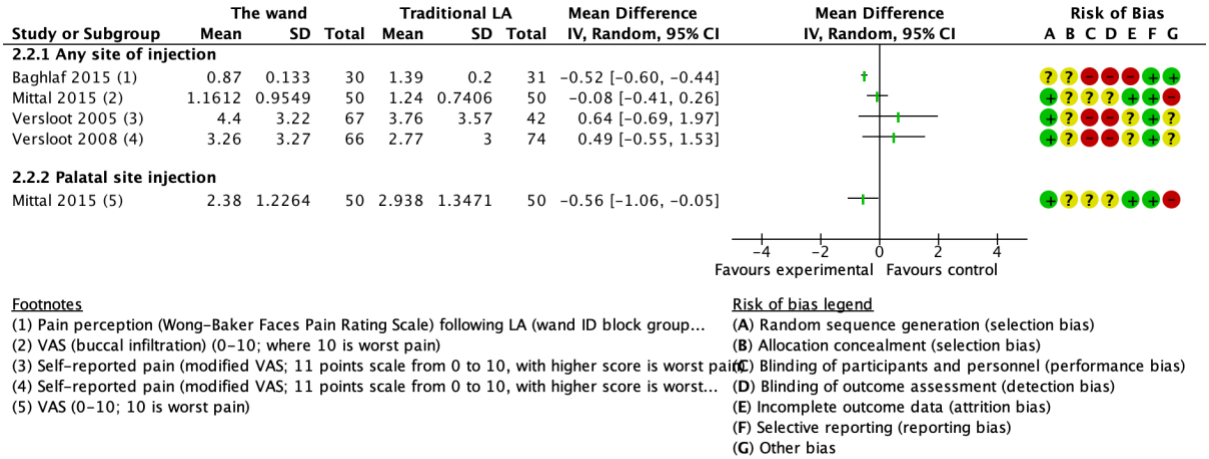
Results from these studies (Tahmassebi 2009; Versloot 2005; Versloot 2008) in this outcome showed no difference in anxiety changes: MD -0.38, 95% CI -0.81 to 0.05; P = 0.089, 109 participants; MD -0.10, 95% CI -0.46 to 0.26; P = 0.59, 140 participants; and MD -0.50, 95% CI -2.27 to 1.27; P = 0.59, 38 participants, respectively, during the injection period when using the wand in delivering LA versus conventional LA (Analysis 2.4) (228, 260, 247).

Other outcomes

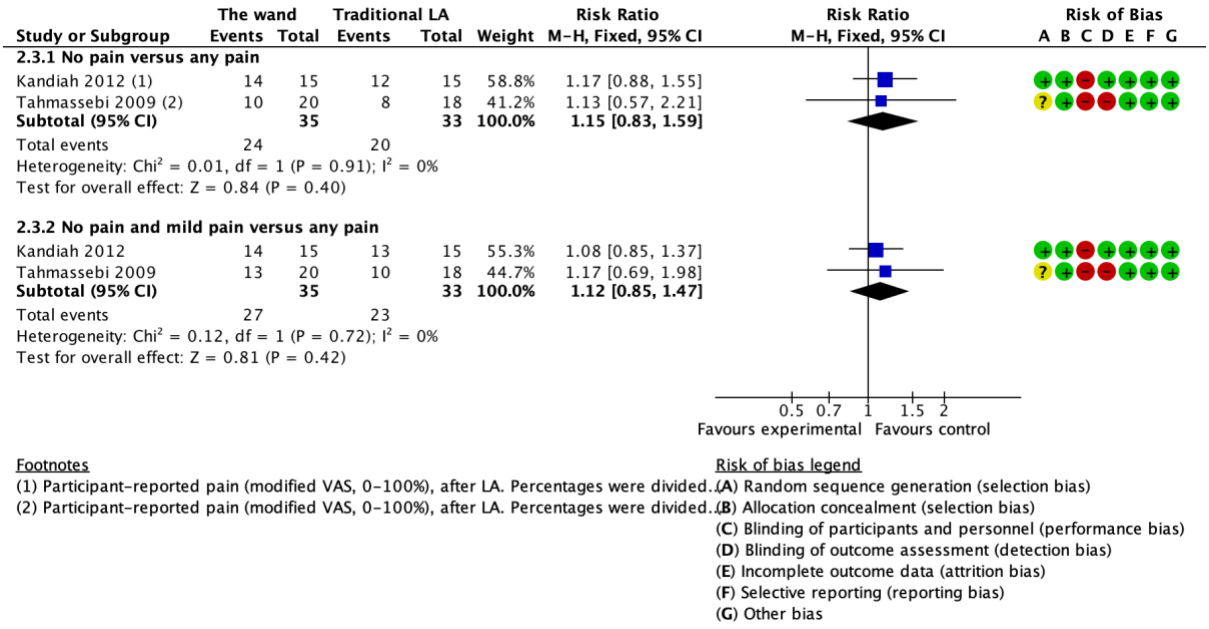
No data on the primary outcome of acceptance of LA, or on any other secondary outcomes including adverse events, were reported.



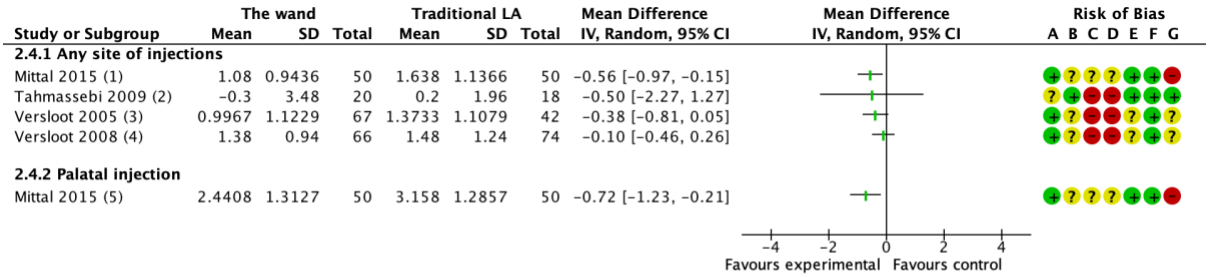
Analysis 2.1: Any disruptive behaviour (body movements, crying, restraint and stoppage of treatment) by the child during LA



Analysis 2.2.: Pain perception/pain experience during the intervention



Analysis 2.3.: Pain perception during the intervention (dichotomous)



Footnotes

(1) SEM scale: using the sound, eyes and motor pain reactions (total scores for SEM range from 0 to...
(2) Venham picture test (anxiety difference as after the injection compared to anxiety before the...
(3) Modified Venham's clinical rating of anxiety prior, at the 1st and 2nd 15−second interval of...
(4) Modified Venham's clinical rating of anxiety prior, at the 1st and 2nd 15−second interval of...
(5) SEM scale: using the sound, eyes and motor pain reactions (total scores for SEM range from 0 to...

Risk of bias legend

(**A**) Random sequence generation (selection bias)
(**B**) Allocation concealment (selection bias)
(**C**) Blinding of participants and personnel (performance bias)
(**D**) Blinding of outcome assessment (detection bias)
(**E**) Incomplete outcome data (attrition bias)
(**F**) Selective reporting (reporting bias)
(**G**) Other bias

Analysis 2.4.: Anxiety changes during the intervention

Comparison 4: the wand versus Sleeper One

One study, at high-risk bias, randomised 118 participants and compared the wand with another electronic system called Sleeper One (225) (Additional Table 6; Appendix 3).

Self- or observational assessment of intraoperative distress/pain/acceptance of treatment during provision of LA

Nieuwenhuizen 2013 compared pain-related behaviour between the wand and Sleeper One and found no statistically significant differences between the two delivery methods (with regard to muscle tension, crying, verbal protest, resistance, and body movement) (MD 0.06, 99% CI 0.01 to 0.11; P = 0.0237) (Analysis 3.1) (225).

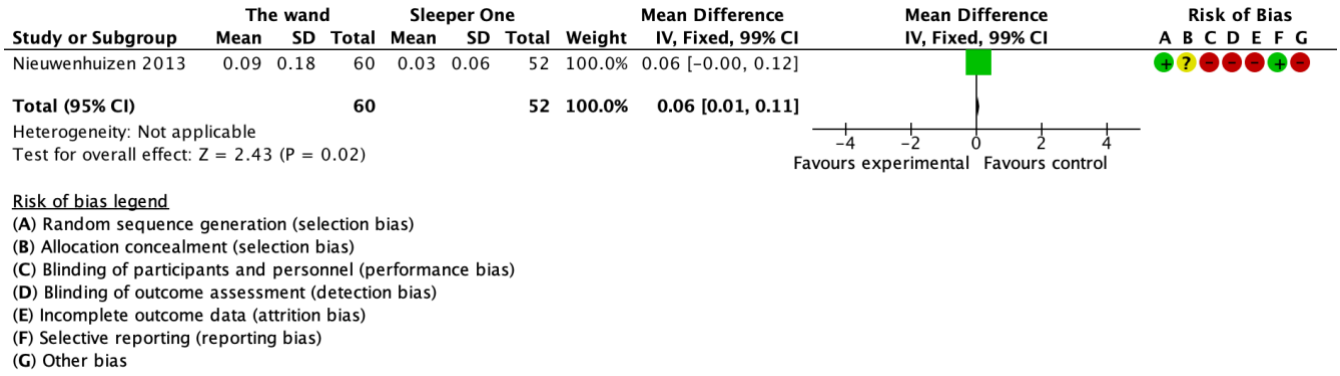
Additionally, children who had Sleeper One injections had no significant different distress and anxiety changes during the injection period compared to the wand (MD 0.46, 99% CI -0.03 to 0.95; P = 0.0197) (Analysis 3.3).

Pain on injection

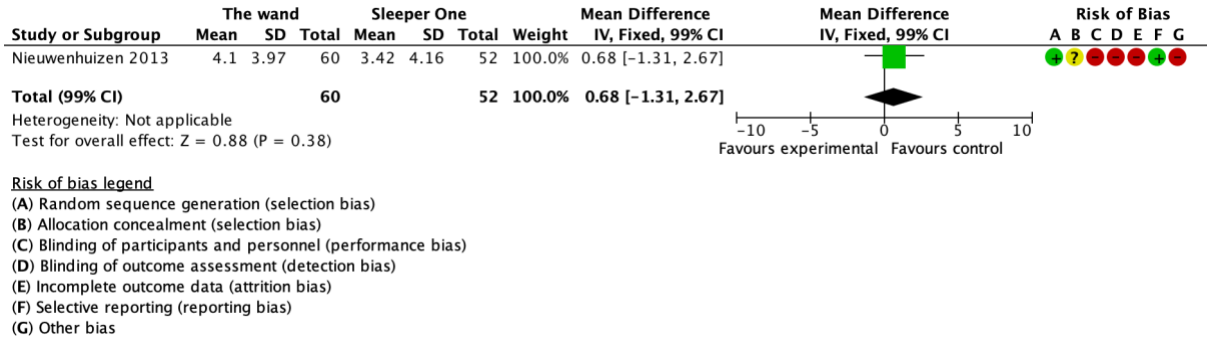
Nieuwenhuizen 2013 reported that self-reported pain was not statistically significantly different between the wand and Sleeper One (MD 0.68, 99% CI -1.31 to 2.67; P = 0.3785, 112 participants) (Analysis 3.2) (225).

Other outcomes

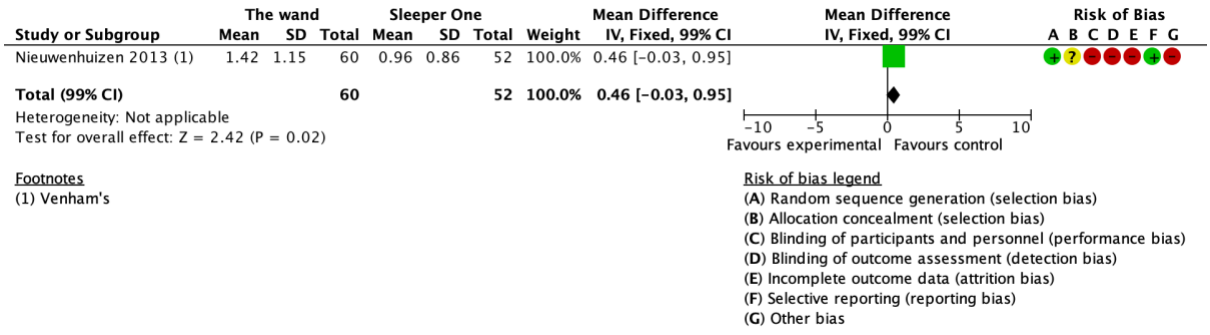
No data on the primary outcome of acceptance of LA, or on any other secondary outcomes including adverse events, were reported (Additional Table 15; Appendix 3).



Analysis 3.1: Any disruptive behaviour (body movements either present or absent during each 15-second interval of the injection phase)



Analysis 3.2: Pain experience (Faces Pain Scale-Revised (FPS-R) 0–10 with higher score indicates worst pain)



Analysis 3.3: Anxiety changes (modified Venham's, 0-6 scale, higher score indicates higher anxiety)

Comparison 5: camouflage syringe versus conventional syringe

One study, at high-risk bias, randomised 143 participants to compare the use of a camouflaging device versus conventional syringe (268).

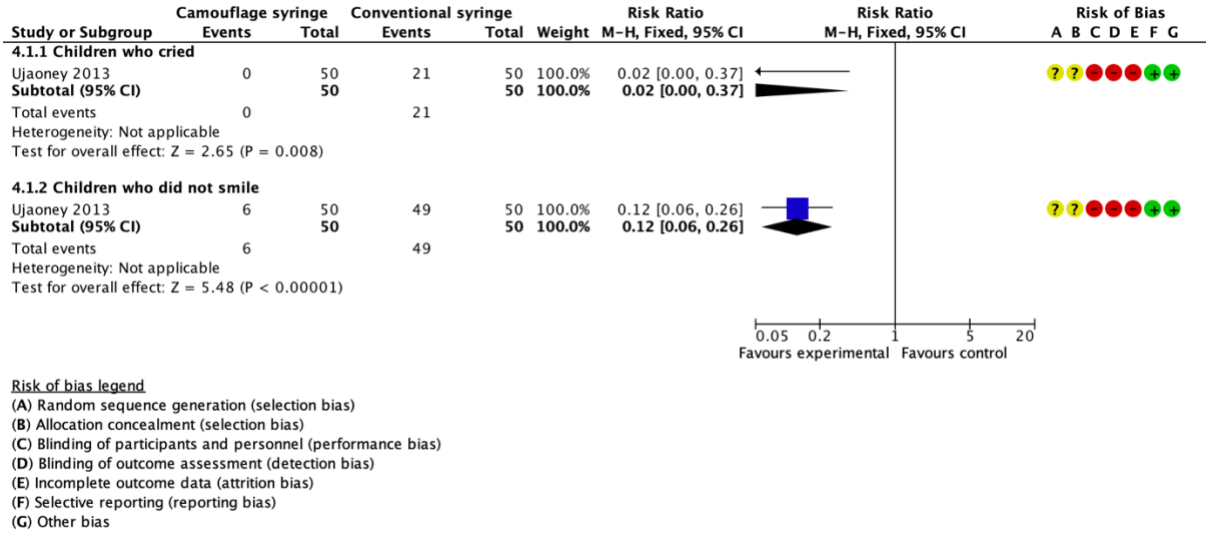
Self- or observational assessment of intraoperative distress/pain/acceptance of treatment during provision of LA

Ujaoney 2013 compared self-reported pain-related behaviour between a conventional and camouflage syringes and found a statistically significance difference in crying and not smiling categories between the camouflage syringe and conventional syringe groups: RR 0.02, 95% CI 0.00 to 0.37 and RR 0.12, 95% CI 0.06 to 0.26, respectively (Analysis 4.1) (268).

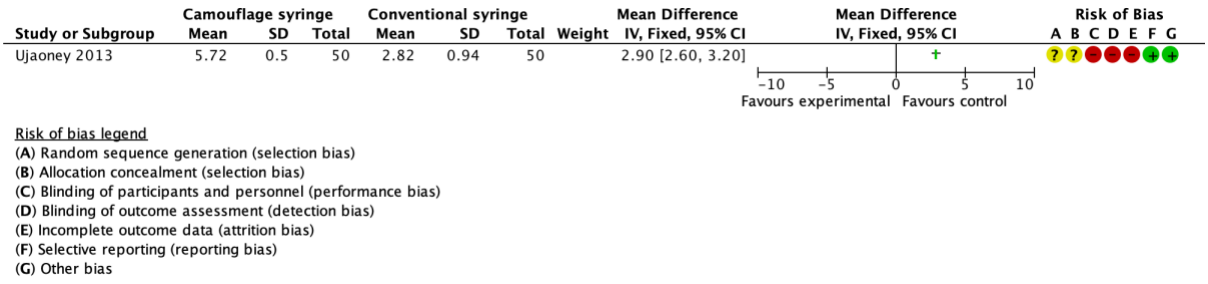
In regard to anxiety and overall behaviour the authors reported significant improvement when using the camouflage syringe. However, according to the reported results, children in the camouflage syringe group had higher Venham's clinical rating with worse overall behaviour for the intervention group (MD 2.90 95% CI 2.60 to 3.20; $P < 0.0001$) as reported by two observers (Cohen's kappa values for behaviour 0.78, $P < 0.0001$) (Analysis 4.2) (Additional Table 7; Appendix 3).

Other outcomes

No data on the primary outcome of acceptance of LA, or on any other secondary outcomes including adverse events, were reported (Additional Table 16; Appendix 3).



Analysis 4.1.1.: Pain-related behaviour



Analysis 4.2: Overall anxiety and behavioural changes (Venham's clinical rating scale, from 0 to 5 with 5 being the worst)

Comparison 6: counter-stimulation or distraction versus conventional treatment

Five studies, at high-risk bias, randomised 512 participants and compared conventional treatment to the following counter-stimulation techniques: pulling the mucosa, intraoral or extraoral finger vibration adjacent to the injection site during delivery of LA, and distraction techniques by asking the patient to do breathing exercises or to draw letters in the air with their feet during delivery of LA (240,262,263,267,277). Another study also at high risk of bias randomised 90 participants and compared the effectiveness of different distraction techniques (passive, active, and passive-active) during LA administration (282). Pooling studies was not appropriate due to heterogeneity in outcome scales and time of outcomes measures across studies.

Self- or observational assessment of intraoperative distress/pain/acceptance of treatment during provision of LA

Lee 2013, with 134 randomised participants, studied the effect of counter-stimulation (by pulling the mucosa) and measured pain experience using a SEM scale (277). The authors found a statistically significant difference, with 76 children reporting no pain (being comfortable) in the treatment group, versus 32 in the control groups and, more markedly, nine children with severe self-reported pain experience in the conventional group versus zero in the treatment group (Additional Table 8; Appendix 3). When the data were re-analysed as any pain versus no pain (mild, moderate, or severe pain), there was a statistically significant difference in pain experience with a higher proportion of children experiencing less pain in the counter-stimulation group versus the conventional group (RR 0.12, 95% CI 0.04 to 0.34) (Analysis 5.1).

Sridhar 2019, with 66 randomised participants, evaluated the effect of distraction (breathing exercise) on pain perception using the Faces, Legs, Activity, Cry, and Consolability (FLACC) scale (267). The authors found a significant difference with participants in the intervention group being more relaxed than in the conventional group. When the reported data were re-analysed as absence of pain versus any pain or discomfort (mild, moderate, or severe pain), there was a statistically significant difference with children in the breathing exercise group experiencing less pain than in the conventional treatment group (RR 0.64, 95% CI 0.50 to 0.83) (Analysis 5.1). Additionally, the authors reported on pain perception using the Wong-Baker Face Scale and found a similar result, with children in the intervention group reporting less

perceived pain in comparison to children in the control group (MD -0.94, 95% CI -1.24 to -0.64) (Analysis 5.2).

Comparison of pulse rates showed no significant difference at all time points (baseline, application of topical anaesthetic, during injection, and after LA) in the counter-stimulation group versus the conventional group, according to Tung 2018 (MD 2.00, 95% CI -2.23 to 6.23; 100 participants) (Analysis 5.3) (262). Additionally, no difference in pulse rates during LA was detected in the distraction (breathing exercises) group versus conventional treatment, according to Sridhar 2019 (MD -1.12, 95% CI -5.47 to 3.23; 66 participants) (Analysis 5.3) (Additional Table 8; Appendix 3) (267).

Pain on injection

Tung 2018, with 100 randomised participants, compared self-reported pain after injection of LA using the Wong-Baker Faces Pain Rating Scale, between counter-stimulation (manual vibration) and conventional treatment groups (262). Although the authors found a slight increase of pain scores in the conventional group, that difference was not significant (MD -0.80, 95% CI -1.86 to 0.26) (Analysis 5.2) (Additional Table 8; Appendix 3).

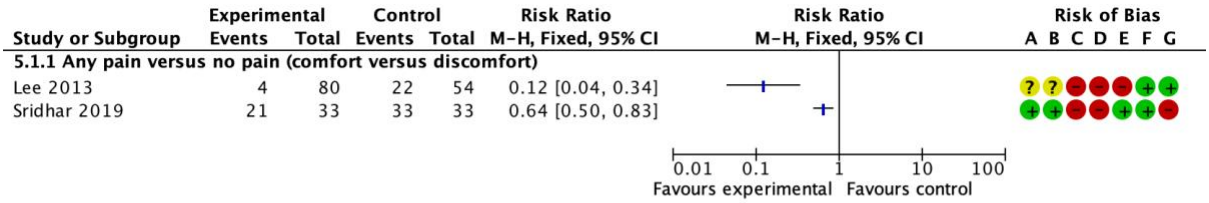
Kamath 2013, with 56 randomised children between the age of 4 and 5 years, measured pain using a modified Toddler-Preschooler Postoperative Pain Scale (TPPPS) (263). The authors compared counter-stimulation (by asking participants to draw letters with their feet during LA administration) to conventional treatment. The author stated that "The use of WITAUL (Writing In The Air Using Leg) was found to be statistically significant compared to the control method with a P value of 0.0001" (MD -3.18, 95% CI -4.26 to -2.10) (Analysis 5.2) (Additional Table 8; Appendix 3). Additionally, the authors reported a similar result in the remaining 104 children, between the age of 6 to 10 years, when evaluated using a FACES Pain Scale–Revised (FPS-R) as children in the intervention group were more comfortable than in the conventional group (MD -3.26, 95% CI -3.95 to -2.57) (Analysis 5.2).

Aminabadi 2008 measured pain/distress using a SEM scale but the reported data were not in a suitable format to present in this review (240). The authors evaluated manual vibration to the soft tissue adjacent to the injection site during injection of LA versus conventional treatment and found lower SEM scale scores for patients in the intervention group. The authors reported that pain reaction was significantly lower in the counter-stimulation group than in the conventional group ($P < 0.05$) (Additional Table 8; Appendix 3).

Abdelmoniem 2016, on the other hand, compared different distraction techniques to each other (passive, active, and passive-active distraction techniques) (271). Participants were asked to listen to music in the passive group and to move their legs up and down alternatively in the active group. Participants in the third group had a combination of these two distraction techniques. Pain perception during LA administration was evaluated using SEM and Wong-Baker Faces Pain Rating Scale and the authors reported a non-significant difference between the three distraction methods (P = 0.743 and P = 0.112 respectively on both scales) (Additional Table 8; Appendix 3).

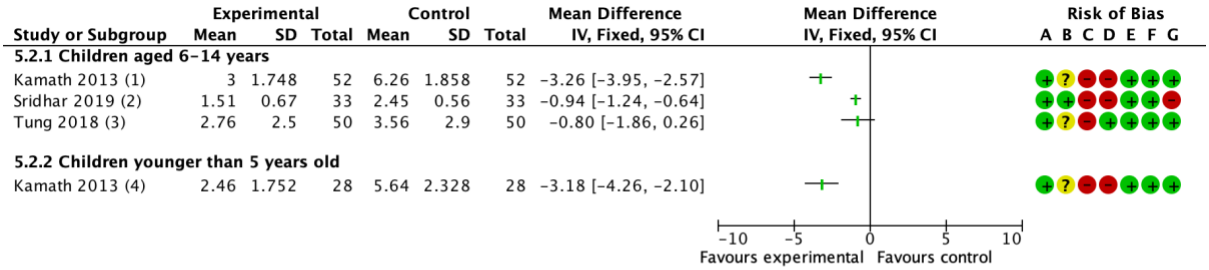
Other outcomes

No data on the primary outcome of acceptance of LA, or on any other secondary outcomes including adverse events, were reported.



Risk of bias legend
(A) Random sequence generation (selection bias)
(B) Allocation concealment (selection bias)
(C) Blinding of participants and personnel (performance bias)
(D) Blinding of outcome assessment (detection bias)
(E) Incomplete outcome data (attrition bias)
(F) Selective reporting (reporting bias)
(G) Other bias

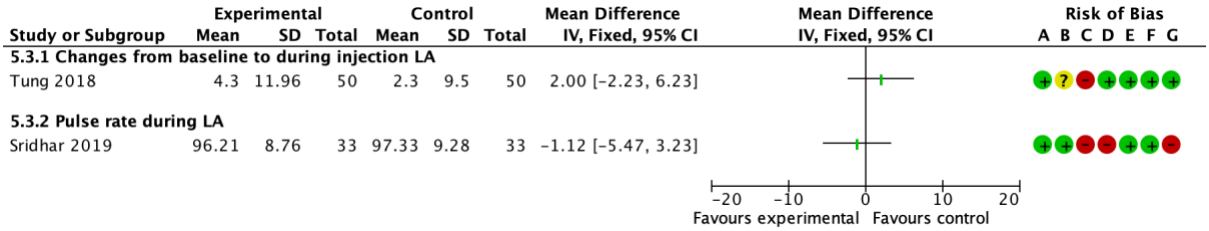
Analysis 5.1: pain versus no pain



Footnotes
(1) FACES Pain Scale Revised (FPS- R) (0-10)
(2) Wong-Baker Faces Pain Rating Scale (6-point scale, higher score indicates worst pain)...
(3) Wong-Baker Faces Pain Rating Scale (0-10 where 10 is the worst pain) (age group 7-14)
(4) Modified Toddler-Preschooler Postoperative Pain Scale (TPPPS) (score 0-8 where 8...

Risk of bias legend
(A) Random sequence generation (selection bias)
(B) Allocation concealment (selection bias)
(C) Blinding of participants and personnel (performance bias)
(D) Blinding of outcome assessment (detection bias)
(E) Incomplete outcome data (attrition bias)
(F) Selective reporting (reporting bias)
(G) Other bias

Analysis 5.2.: Pain perception



Risk of bias legend
(A) Random sequence generation (selection bias)
(B) Allocation concealment (selection bias)
(C) Blinding of participants and personnel (performance bias)
(D) Blinding of outcome assessment (detection bias)
(E) Incomplete outcome data (attrition bias)
(F) Selective reporting (reporting bias)
(G) Other bias

Analysis 5.3.1: Anxiety changes (pulse rates)

Comparison 7: electrical counter-stimulation device (DentalVibe) versus conventional LA

One study, at high risk of bias, compared electric vibration (DentalVibe) adjacent to the injection site during delivery of LA, with conventional treatment (Additional Table 9; Appendix 3) (262).

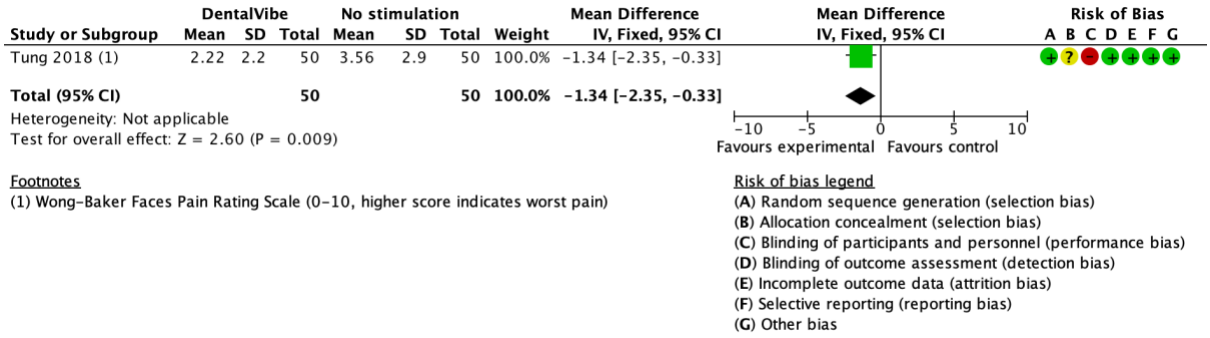
Self- or observational assessment of intraoperative distress/pain/acceptance of treatment during provision of LA

Tung 2018, with 100 randomised participants, compared self-reported pain after the injection of LA using the Wong-Baker Faces Pain Rating Scale, between DentalVibe (counter-stimulation) and conventional treatment group and found a significant reduction in pain scores in the DentalVibe group (MD -1.34, 95% CI -2.35 to -0.33) (Analysis 6.1) (262).

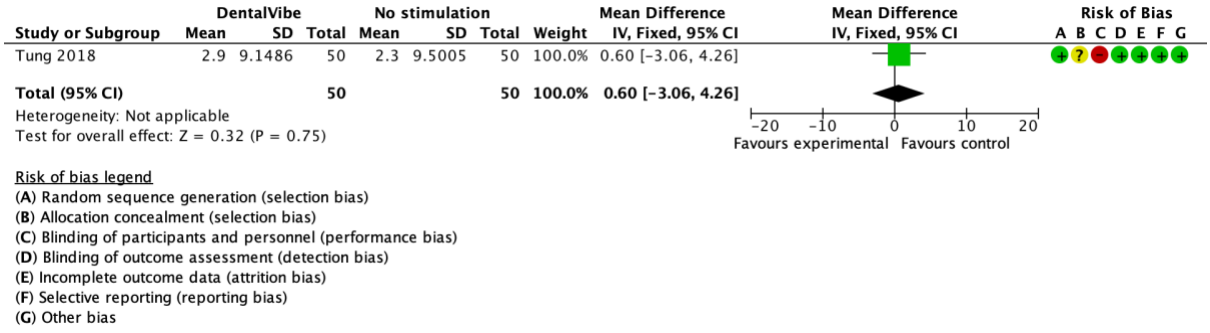
Comparison of pulse rates showed no significant difference at all time points (baseline, application of topical anaesthetic, during the injection, and after LA) in the DentalVibe group versus the conventional according to Tung 2018 (MD 0.60, 95% CI -3.06 to 4.26) (Analysis 6.2).

Other outcomes

No data on the primary outcome of acceptance of LA, or on any other secondary outcomes including adverse events, were reported (Additional Table 17; Appendix 3).



Analysis 6.1: Pain experience (self-reported pain)



Analysis 6.2.: Anxiety changes (pulse rates changes from baseline to during injection recorded pulse rates)

Comparison 8: counter-stimulation and distraction, versus conventional treatment

One study, at high-risk bias, randomised 5278 participants, and compared counter-stimulation and distraction versus conventional treatment. Patients were asked to raise their legs in turn, while having manual vibration to the soft tissue adjacent to the injection site during delivery of LA (240).

Self- or observational assessment of intraoperative distress/pain/acceptance of treatment during provision of LA

Aminabadi 2008 measured distress using a SEM scale and found lower distress values in the combined counter-stimulation and distraction group versus conventional LA (240). This difference was significant when compared to the conventional group, according to the authors (Additional Table 10; Appendix 3).

Other outcomes

No data on the primary outcome of acceptance of LA, or on any other secondary outcomes including adverse events, were reported (Additional Table 18; Appendix 3).

Comparison 9: hypnosis versus conventional treatment

Three studies, at high risk of bias, randomised 170 participants and compared hypnosis during delivery of LA with conventional treatment (242,266,279).

Self- or observational assessment of intraoperative distress/pain/acceptance of treatment during provision of LA

Huet 2011 measured pain using a using a modified objective pain score (0 to 10) with 0 indicating no pain and 10 a maximum of pain (242). The authors reported that participants in the hypnosis group had a significant lower pain experience during the delivery of LA than in the conventional group (MD -1.79, 95% CI -3.01 to -0.57: 29 participants) (Analysis 7.1). Additionally, the authors measured self-reported pain after LA using VAS (0 to 10) and results were similar to the author's previous finding. When the VAS was re-analysed as a dichotomous variable with a threshold of 3 to define a strong pain experience, the authors reported a significant lower pain experience in the hypnosis group compared to the conventional group after LA (RR 0.24, 95% CI 0.06 to 0.92) (Analysis 7.2) (Additional Table 11; Appendix 3).

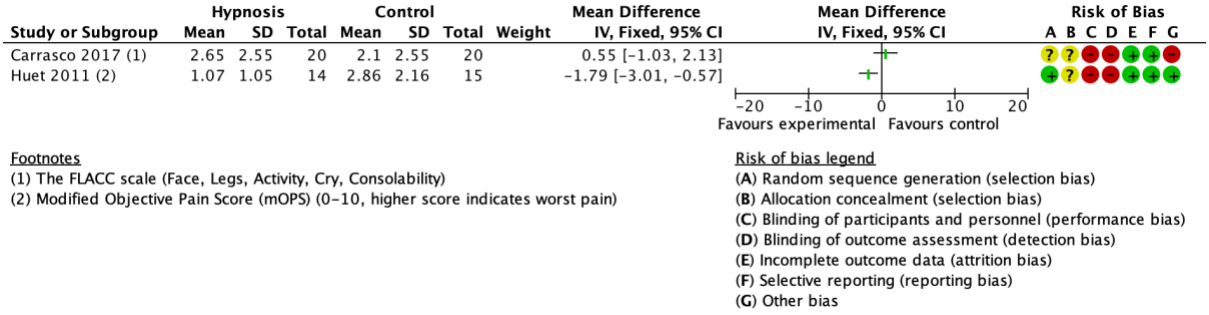
Carrasco 2017, with 40 randomised participants, measured pain perception using the FLACC scale (279). The authors reported no statistically significant differences in pain perception between the hypnosis group and the conventional treatment group (MD 0.55, 95% CI -1.03 to 2.13) (Analysis 7.1).

Oberoi 2016, with 200 randomised participants, measured physical or verbal resistance from baseline to the time of the injection and reported that significant more participants showed resistance in the control group than in the hypnosis group (RR 0.47, 95% CI 0.34 to 0.65) (Analysis 7.3) (Additional Table 11; Appendix 3) (266).

Carrasco 2017 reported a marginal statistical difference (P = 0.05) in pulse rates between baseline and LA delivery in the hypnotic group (279). However, that difference was not significant when we attempted to re-analyse the pulse rate between groups at the same time points, either before or during injection (MD -1.85, 95% CI -11.21 to 7.51 and MD -5.73, 95% CI -14.35 to 2.89, respectively) (Analysis 7.4). Oberoi 2016 comparison of pulse rate after LA showed a significant increase in the control group versus the hypnotic group (MD -15.06, 95% CI -16.37 to -13.75) (Analysis 7.4) (Additional Table 11; Appendix 3).

Other outcomes

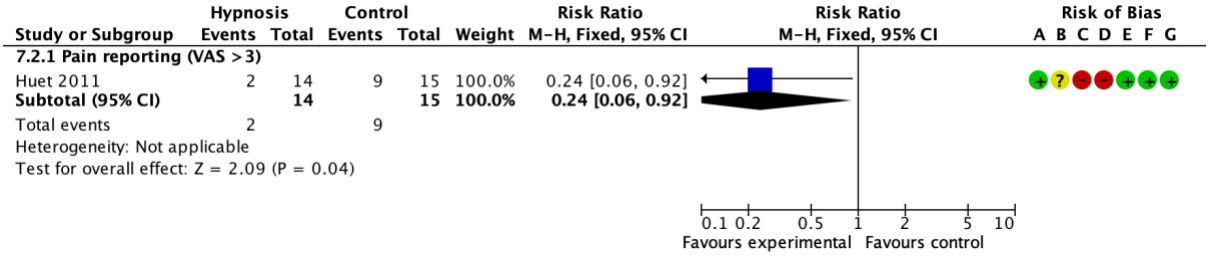
No data on the primary outcome of acceptance of LA, or on any other secondary outcomes including adverse events, were reported.



Footnotes
(1) The FLACC scale (Face, Legs, Activity, Cry, Consolability)
(2) Modified Objective Pain Score (mOPS) (0–10, higher score indicates worst pain)

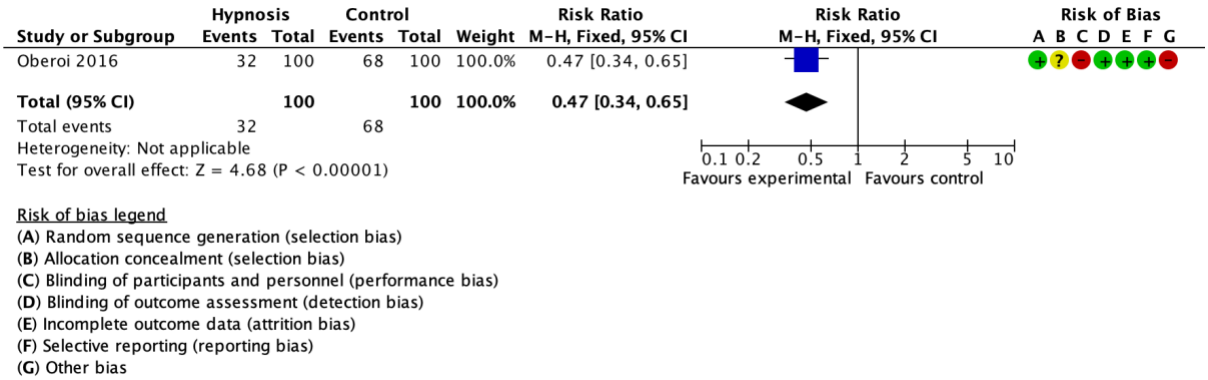
Risk of bias legend
(A) Random sequence generation (selection bias)
(B) Allocation concealment (selection bias)
(C) Blinding of participants and personnel (performance bias)
(D) Blinding of outcome assessment (detection bias)
(E) Incomplete outcome data (attrition bias)
(F) Selective reporting (reporting bias)
(G) Other bias

Analysis 7.1: Pain perception

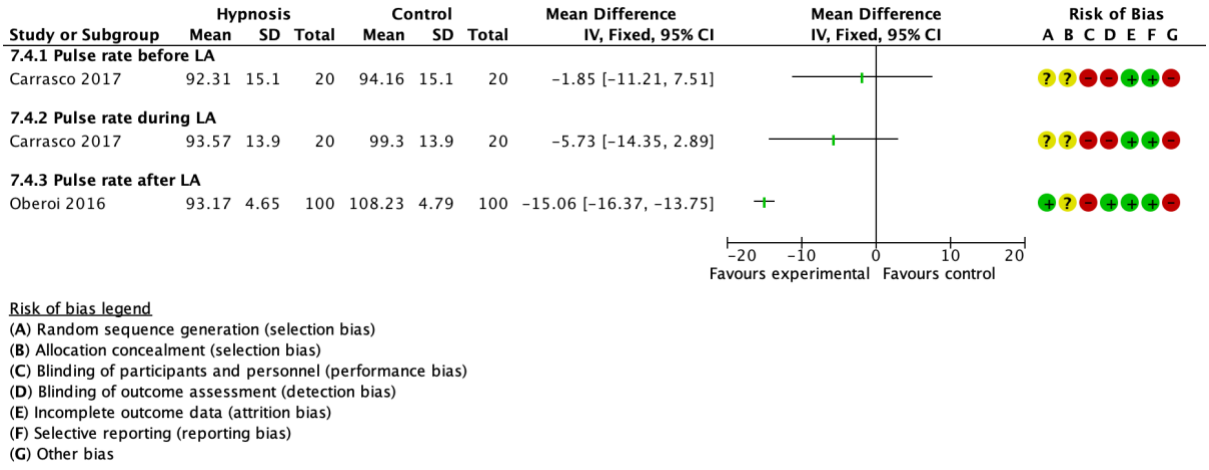


Risk of bias legend
(A) Random sequence generation (selection bias)
(B) Allocation concealment (selection bias)
(C) Blinding of participants and personnel (performance bias)
(D) Blinding of outcome assessment (detection bias)
(E) Incomplete outcome data (attrition bias)
(F) Selective reporting (reporting bias)
(G) Other bias

Analysis 7.2: Pain experience (dichotomous - VAS, 0-10, higher score indicates worst pain)



Analysis 7.3: Anxiety (number of participants that exhibit physical or verbal resistance to LA - dichotomous)



Analysis 7.4.1.: Physiological assessment - pulse rates

Comparison 10: video modelling acclimatisation for LA versus oral hygiene video

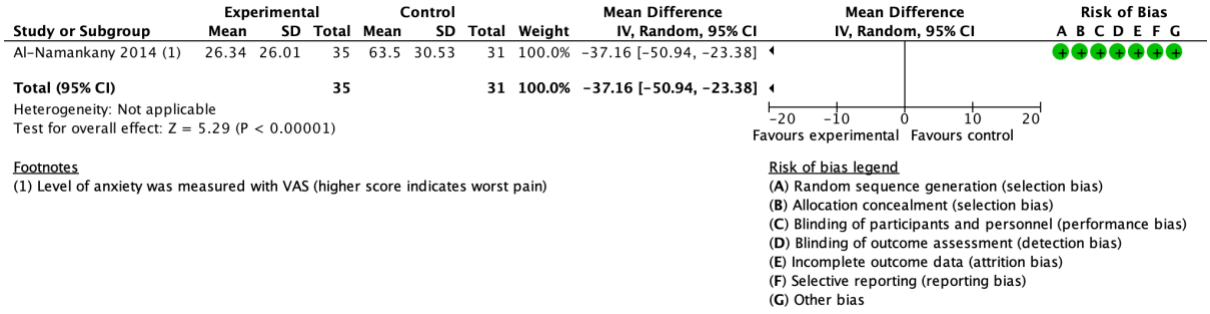
Al-Namankany 2014, at low risk bias, with 80 randomised and 66 evaluated participants, compared the video modelling for LA with video modelling for oral hygiene (255).

Self- or observational assessment of intraoperative distress/pain/acceptance of treatment during provision of LA

Al-Namankany 2014 compared the video modelling for LA delivery with video modelling for oral hygiene using VAS and found statistically significant reduction in distress during delivery of LA when the LA video modelling was shown, in comparison to the oral hygiene video group (MD -37.16, 95% CI –50.94 to -23.38; P < 0.0001) (Analysis 8.1) (Additional Table 12; Appendix 3) (255).

Other outcomes

No data on the primary outcome of acceptance of LA, or on any other secondary outcomes including adverse events, were reported (Additional Table 19; Appendix 3).



Analysis 8.1: Anxiety

Comparison 11: video modelling acclimatisation versus acclimatisation in clinic

One study at high risk bias, randomised 46 participants and compared the acclimatisation using video modelling with conventional acclimatisation (tell-show-do alone in clinic), prior to treatment (259).

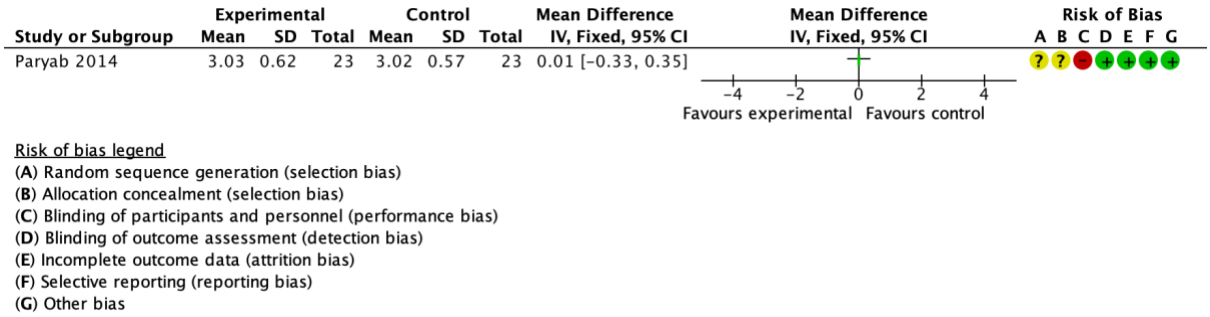
Self- or observational assessment of intraoperative distress/pain/acceptance of treatment during provision of LA

Paryab 2014 measured co-operation behaviour levels using Frankl scales and found no significant difference between children in the video modelling and tell-show-do alone groups (MD 0.01, 95% CI –0.33 to 0.35; P = 0.9548) (Analysis 9.1) (Additional Table 13; Appendix 3) (259).

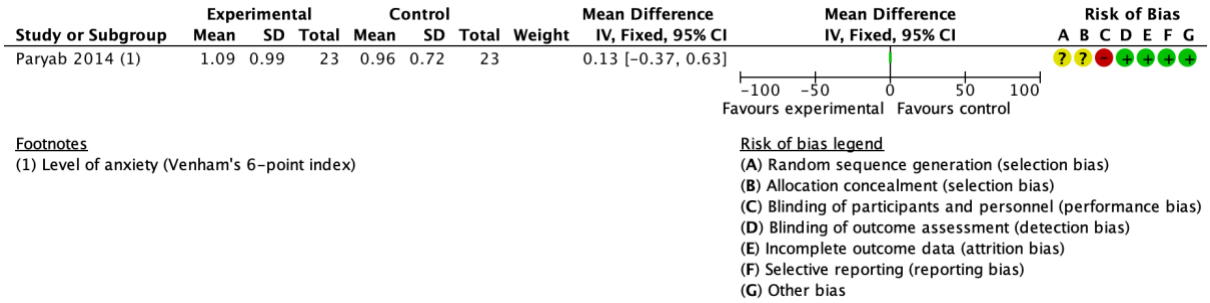
Paryab 2014 also measured anxiety (Venham's scale), and found no significant difference between children in both groups (MD 0.13, 95% CI –0.37 to 0.63; P = 0.6131) (Analysis 9.2) (259). Similarly, the authors reported no significant differences between both groups in heart rate changes before and after LA injection among the participants (P = 0.6) (Additional Table 13).

Other outcomes

No data on the primary outcome of acceptance of LA, or on any other secondary outcomes including adverse events, were reported (Additional Table 20; Appendix 3).



Analysis 9.1: Co-operative behaviour level using Frankl 4-point index



Analysis 9.2: Anxiety changes (6-point index, higher score indicates worst anxiety)

4.6 Summary of findings tables

Audiovisual distraction compared to conventional treatment for increasing acceptance of LA in children and adolescents having dental treatment						
Patient or population: children and adolescents having dental treatment **Setting:** dental clinic **Intervention:** audiovisual distraction **Comparison:** conventional treatment						
Outcomes	**Anticipated absolute effects*** **(95% CI)**		**Relative effect (95% CI)**	**Number of participants (studies)**	**Certainty of the evidence (GRADE)**	**What this means**
	Risk with conventional treatment	**Risk with audiovisual distraction**				
Acceptance of LA	Included studies did not report on this outcome					
Completion of dental treatment	Included studies did not report on this outcome					
Successful LA/painless treatment	Included studies did not report on this outcome					
Self- or observational assessment of intraoperative distress/pain/acceptance of treatment during provision of LA: pain-related behaviour during LA (children who exhibited a negative versus positive behaviour; Frankl Behaviour Rating Scale (FBRS))	**Study population**		RR 0.13 (0.03 to 0.50)	60 (1 RCT)	⨁⊖⊖⊖ VERY LOW[a]	Evidence is uncertain regarding the effect of audiovisual distraction on negative behaviour
	533 per 1000	69 per 1000 (16 to 267)				
Patient satisfaction: measured by questionnaires	Included studies did not report on this outcome					

Adverse effects	Included studies did not report on this outcome

[*]**The risk in the intervention group** (and its 95% CI) is based on the assumed risk in the comparison group and the **relative effect** of the intervention (and its 95% CI)

CI: confidence interval; **LA:** local anaesthetic; **MD:** mean difference; **RCT:** randomised controlled trial; **RR:** risk ratio; **VR:** virtual reality

GRADE Working Group grades of evidence
High certainty: we are very confident that the true effect lies close to that of the estimate of the effect
Moderate certainty: we are moderately confident in the effect estimate: the true effect is likely to be close to the estimate of the effect, but there is a possibility that it is substantially different
Low certainty: our confidence in the effect estimate is limited: the true effect may be substantially different from the estimate of the effect
Very low certainty: we have very little confidence in the effect estimate: the true effect is likely to be substantially different from the estimate of effect

Table 7: Summary of findings table: Audiovisual distraction compared to conventional treatment

Footnotes

[a]Certainty of the evidence downgraded by 1 level for high risk of bias, and 2 levels for very serious imprecision (single study with a small sample size).

The wand compared to traditional LA for increasing acceptance of LA in children and adolescents having dental treatment						
Patient or population: children and adolescents having dental treatment **Setting:** dental clinic **Intervention:** the wand **Comparison:** traditional LA						
Outcomes	**Anticipated absolute effects*** **(95% CI)**		**Relative effect (95% CI)**	**Number of participants (studies)**	**Certainty of the evidence (GRADE)**	**What this means**
	Risk with traditional LA	**Risk with the wand**				
Acceptance of LA	Included studies did not report on this outcome					
Completion of dental treatment	Included studies did not report on this outcome					
Successful LA/painless treatment	Included studies did not report on this outcome					
Self- or observational assessment of intraoperative distress/pain/acceptance of treatment during provision of LA: pain-related behaviour (any disruptive behaviour/sudden reaction/movement)	4 studies reported a benefit in using the wand while the remaining studies results suggested no difference between the 2 methods of delivering LA			704 (6 RCTs)	⨁⊖⊖⊖ VERY LOW[a]	Evidence is uncertain regarding the effect of the wand on negative behaviour Pooling of studies was not appropriate due to heterogeneity in outcome scales, sites of injection, and time of outcome measures
Patient satisfaction: measured by questionnaires	Included studies did not report on this outcome					
Adverse effects	Included studies did not report on this outcome					
*__The risk in the intervention group__ (and its 95% CI) is based on the assumed risk in the comparison group and the **relative effect** of the intervention (and its 95% CI)						

CI: confidence interval; **LA:** local anaesthetic; **MD:** mean difference; **RCT:** randomised controlled trial; **RR:** risk ratio; **VAS:** visual analogue scale

GRADE Working Group grades of evidence
High certainty: we are very confident that the true effect lies close to that of the estimate of the effect
Moderate certainty: we are moderately confident in the effect estimate: the true effect is likely to be close to the estimate of the effect, but there is a possibility that it is substantially different
Low certainty: our confidence in the effect estimate is limited: the true effect may be substantially different from the estimate of the effect
Very low certainty: we have very little confidence in the effect estimate: the true effect is likely to be substantially different from the estimate of effect

Table 8: Summary of findings table: The wand compared to traditional local anaesthetic

Footnotes

[a]Certainty of the evidence downgraded by 1 level for high risk of bias, and 2 levels for very serious imprecision.

Counter-stimulation or distraction compared to conventional treatment for increasing acceptance of LA in children and adolescents having dental treatment						
Patient or population: children and adolescents having dental treatment **Setting:** dental clinic **Intervention:** counter-stimulation or distraction **Comparison:** conventional treatment						
Outcomes	**Anticipated absolute effects[*] (95% CI)**		**Relative effect (95% CI)**	**Number of participants (studies)**	**Certainty of the evidence (GRADE)**	**What this means**
	Risk with conventional treatment	**Risk with counter-stimulation or distraction**				
Acceptance of LA	Included studies did not report on this outcome					
Completion of dental treatment	Included studies did not report on this outcome					
Successful LA/painless treatment	Included studies did not report on this outcome					
Self- or observational assessment of intraoperative distress/pain/acceptance of treatment during provision of LA: pain (Sound, Eyes, and Motor (SEM) scale; dichotomous - any pain versus no pain, higher score indicates high pain experience)	**Study population**		RR 0.12 (0.04 to 0.34)	134 (1 RCT)	⨁⊖⊖⊖ VERY LOW[a]	Evidence is uncertain regarding the effect of counter-stimulation on pain
	407 per 1000	49 per 1000 (16 to 139)				
Patient satisfaction: measured by questionnaires	Included studies did not report on this outcome					
Adverse effects	Included studies did not report on this outcome					

*__The risk in the intervention group__ (and its 95% CI) is based on the assumed risk in the comparison group and the **relative effect** of the intervention (and its 95% CI) **CI:** confidence interval; **LA:** local anaesthetic; **MD:** mean difference; **RCT:** randomised controlled trial; **RR:** risk ratio
GRADE Working Group grades of evidence **High certainty:** we are very confident that the true effect lies close to that of the estimate of the effect **Moderate certainty:** we are moderately confident in the effect estimate: the true effect is likely to be close to the estimate of the effect, but there is a possibility that it is substantially different **Low certainty:** our confidence in the effect estimate is limited: the true effect may be substantially different from the estimate of the effect **Very low certainty:** we have very little confidence in the effect estimate: the true effect is likely to be substantially different from the estimate of effect

Table 9: Summary of findings table: Counter-stimulation or distraction compared to conventional treatment

Footnotes

[a] Certainty of the evidence downgraded by 1 level for high risk of bias, and 2 levels for very serious imprecision (single study with a small sample size).

Hypnosis compared to conventional treatment for increasing acceptance of LA in children and adolescents having dental treatment						
Patient or population: children and adolescents having dental treatment **Setting:** dental clinic **Intervention:** hypnosis **Comparison:** conventional treatment						
Outcomes	**Anticipated absolute effects*** **(95% CI)**		**Relative effect (95% CI)**	**Number of participants (studies)**	**Certainty of the evidence (GRADE)**	**What this means**
	Risk with conventional treatment	**Risk with hypnosis**				
Acceptance of LA	Included studies did not report on this outcome					
Completion of dental treatment	Included studies did not report on this outcome					
Successful LA/painless treatment	Included studies did not report on this outcome					
Self- or observational assessment of intraoperative distress/pain/acceptance of treatment during provision of LA: pain (Modified Objective Pain Score (mOPS); VAS: 0 to 10, higher score indicates worse pain experience)	Conventional group mean was 2.86	MD 1.79 lower (3.01 lower to 0.57 lower)	-	29 (1 RCT)	⨁⊖⊖⊖ VERY LOW[a]	Evidence is uncertain regarding the effect of hypnosis on pain
Patient satisfaction: measured by questionnaires	Included studies did not report on this outcome					
Adverse effects	Included studies did not report on this outcome					
*__The risk in the intervention group__ (and its 95% CI) is based on the assumed risk in the comparison group and the **relative effect** of the intervention (and its 95% CI)						

CI: confidence interval; **LA:** local anaesthetic; **MD:** mean difference; **RCT:** randomised controlled trial; **RR:** risk ratio; **VAS:** visual analogue scale
GRADE Working Group grades of evidence **High certainty:** we are very confident that the true effect lies close to that of the estimate of the effect **Moderate certainty:** we are moderately confident in the effect estimate: the true effect is likely to be close to the estimate of the effect, but there is a possibility that it is substantially different **Low certainty:** our confidence in the effect estimate is limited: the true effect may be substantially different from the estimate of the effect **Very low certainty:** we have very little confidence in the effect estimate: the true effect is likely to be substantially different from the estimate of effect

Table 10: Summary of findings table: Hypnosis compared to conventional treatment

Footnotes

[a] Certainty of the evidence downgraded by 1 level for high risk of bias, and 2 levels for very serious imprecision (single study with a small sample size).

4.7 Discussion

Summary of main results

The objective of this review was to assess the effects of different interventions on increasing acceptance of LA in children and adolescents. Interventions were delivered in advance of the injection, immediately prior to LA delivery, or during injection or subsequent treatment or both. We found 26 eligible trials for inclusion, of which nine were on the wand versus conventional LA comparison and six on the counter-stimulation or distraction versus conventional LA comparison. Hypnosis versus conventional LA was compared in three studies and three studies were also included in the audiovisual distraction versus conventional LA comparison. The remaining comparisons had a single study each.

No studies reported on our primary outcome of acceptance of local anaesthetic (LA). Secondary outcomes included: pain on injection (measured by pain perception or experience), self- or observational assessments of intraoperative distress/pain/acceptance of treatment and pre or postoperative anxiety measures (measured using physiological assessments, questionnaires, anxiety scales, and behavioural assessment). No studies reported on the following secondary outcomes: completion of dental treatment, successful LA/painless treatment, patient satisfaction, parent satisfaction, and adverse events.

There was a wide discrepancy in intervention methodologies, measures, and time points for outcome assessment rendering interpretation of the data very difficult. Equally timing of the interventions varied, mostly between immediately before to during LA/injection. Pooling of studies within a comparison was not possible in most cases as even where studies used the same scales, they were adapted differently to each study, and administrated at different time points during treatment. Due to the limitations of the evidence at hand, we could only include two studies in a meta-analysis of one comparison (the wand versus conventional LA), and their pooled estimates revealed no difference (very low-certainty evidence). The findings from the other comparisons were insufficient to draw any affirmative conclusions about their effectiveness over conventional LA, and were considered to be very low-certainty evidence.

None of the evaluated interventions showed to be beneficial over conventional delivery of LA. In a small number of individual studies, interventions were reported to be more effective than conventional LA, however included trials were at high risk of bias (with the exception of Al-Namankany 2014) (255), and most comparisons were of a single trial. For this reason, we feel

that there is insufficient evidence at this time to conclude as to the best intervention for increasing acceptance of dental LA in children. Our results highlight the need for employing robust methodology and for better reporting trials in this area of dentistry.

While we have attempted to include children with SHCNs in our review, we found no studies that met our inclusion criteria. Therefore, no reliable evidence about acceptance of dental LA in children and adolescents with SHCNs was found. We urge trialists conducting future RCTs to include children and adolescent with SHCNs, it would be beneficial to report on in order to increase acceptance of LA. This is really important to report on especially in Saudi Arabia as some evidence reported limited access to dental care for children with SHCNs in the country and pain associated with LA can limit or hinder their access to care (283). More studies assessing acceptance of LA in children with SHCNs in order to further support the body of evidence in delivering dental care and help with minimizing pain experiences during dental treatment are needed.

Overall completeness and applicability of evidence

This Cochrane Review excluded measurements taken for the overall dental treatment (i.e. anxiety or distress measurements taken during or at the end of appointments) as we felt this might introduce bias due to the wide variation of treatments provided. Furthermore, we felt that it would be an evaluation of the whole dental treatment and not only of the intervention for LA delivery. Some trials restricted their inclusion to patients with low baseline anxiety or separated the groups according to their anxiety level which may not be a representative of the general population. When researchers reported on general outcomes and subsequently split participants into different groups based on their anxiety or experience level, we reported on outcomes before any amendment was taken, whenever possible.

Although we found 26 eligible trials for inclusion and we had two comparisons with a reasonable number of studies, we were unable to answer the review's question due to methodological weakness and the limited number of studies in most comparisons. It is unfortunate that we were not able to advocate any intervention but with such limited evidence, we were precluded from doing so. We urge future researchers to standardise measures and clarify their use with better reporting in order to maximise the usefulness of their research findings in practice.

We found no studies that met our inclusion criteria for this review and included children or adolescents with special healthcare needs. Therefore, we found no reliable evidence about acceptance of dental LA in children and adolescents with special care needs. This area of evidence is limited, and a well-designed trial should be undertaken in order to explore the best available approach for delivering dental LA for this group.

We identified seven ongoing studies (see Characteristics of ongoing studies) and one study is awaiting classification (Characteristics of studies awaiting classification) which may be included in the update of this review.

Quality of the evidence

One of the included studies was assessed as being at low risk of bias (255). The remaining trials were at high risk of bias for at least one domain. The overall certainty of the body of evidence for all comparisons was very low. The evidence was downgraded by one level for serious risk of bias, and two levels for very serious imprecision. This was due to methodological weakness, and inconsistency in the reporting of outcomes and outcome measures. Many of the included trials had a small number of participants and may have had insufficient sample sizes to determine a difference between interventions.

In studies where the intervention was delivery of LA with electronic devices, there were wide variations in regard to speed of LA delivery. Two authors had similar speeds for delivery of LA using conventional or electronic devices. Other authors showed considerably different speeds, with conventional LA delivered much quicker than electronic LA. Studies performed in adults have reported that speed of injection significantly influences comfort during LA delivery (285), and for this reason variations may have introduced bias. Furthermore, as the operators could not be blinded to the intervention it is possible that the difference in delivery times might have been a result of operator's knowledge, leading to bias. Perhaps standardised speeds of LA delivery might have been more accurate in evaluating the benefits of electronic devices over conventional syringes. On the other hand, one may argue that slow delivery of LA is one of the advantages of electronic devices in comparison to conventional LA.

One area of limitation that was apparent when conducting the review was the lack of clarity on how and when outcomes were measured, with great variation between trials on how they were

reported on. Researchers also reported on outcomes using a variety of scales with different interpretation, making it impossible to standardise or pool these data.

Overall risk of bias was high for most studies, mostly arising from lack of blinding of participants due to the nature of the interventions. Sample size calculations were not always performed (10 trials), with others either not carrying it out or not reporting it; hence it is possible that a number of trials lacked statistical power to detect differences between different arms.

Potential biases in the review process

Every attempt was made to limit bias in the review process by using a broad search strategy of several databases without language restrictions for potentially eligible studies. The authors independently assessed studies for eligibility and undertook subsequent data extraction and risk of bias assessment to minimise additional bias. We acknowledge, however, that the decision to report on body movement as a sign of disruptive behaviour may be considered a bias by the readers. The decision was reached as it was frequently reported across studies and other findings were not clear or adequately reported. We assumed that authors reported all outcomes described in their trials.

Agreements and disagreements with other studies or reviews

We are not aware of any comprehensive reviews on interventions to increase the acceptance of LA in children and adolescents.

4.8 Authors' conclusions

Implications for practice

We did not find sufficient evidence to draw firm conclusions as to the best interventions to increase acceptance of local anaesthetic (LA) in children and adolescents, due to wide variation in methodology, outcome measures, and interventions of the included studies. All evidence was rated as very low certainty.

Implications for research

Based on the literature review and the results of this Cochrane Review, we suggest the following research recommendations.

- Further randomised controlled trials (RCTs) should be conducted in children, in order to assess the effects of different interventions in increasing acceptance of LA.
- Parallel trials are preferable to cross-over trials, as the level of baseline anxiety on the second appointment is dependent on the success of the first intervention.
- Parallel trials are preferable to split-mouth trials, as the effects of the intervention cannot be assumed to be limited to a specific site.
- Blinding of all participants should be carefully considered and undertaken as permitted by the study design.
- Sample size calculations should be undertaken.
- Consideration should be given on the standardising delivery of LA and the adjuvant behaviour interventions in all arms.
- Baseline anxiety and demographic information should be reported.
- RCTs should be reported in line with the CONSORT Statement.
- Trial protocols should be made available to facilitate assessment of selective reporting.
- Including parents and caregivers of children and adolescent with SHCNs in plaining future care in the scare of evidence in the area of delivery of LA is an important step.
- Exploring and analysing the perceptions of parents through qualitative research may shed light on ways to increase acceptance of dental treatment including LA and evaluate existing oral care for children with SHCNs.

CHAPTER FIVE

Parental perceptions and experience of delivered oral care for children with special healthcare needs in Saudi Arabia: A qualitative exploration

5.1 Abstract

Aim: The maintenance of oral health is important for all children and especially those with special healthcare needs (SHCNs), who are more vulnerable than others. This study aimed to explore the perceptions as well as the experiences of caregivers and parents relating to oral care delivery, oral health practice and provision of care for children with SHCNs in Saudi Arabia.

Methods: A qualitative study with parents using semi-structured interviews was undertaken to investigate the oral care provided for children with SHCNs. Thematic analysis was employed in this study. The participants were parents of children aged 7 to 11 years old with SHCNs living in the city of Riyadh. All the interviews were conducted in Arabic, transcribed and then translated into English.

Results: 12 caregivers and parents participated in this study. Several themes were identified: the importance of oral health, the role of parents, oral care experiences relating to dental appointments, existing issues with the current oral care provided, and parental views of best practice. Several issues regarding oral care experiences from the parents' viewpoint were discussed. Lack of communication, behavioural issues, waiting time, lack of continuity of care, a limited number of specialised dentists to meet specific needs and lack of knowledge about oral care practices and preventive measures among parents were some of the concerns highlighted in this study.

Conclusion: The findings suggest the need for improvements to the entire network of dental care in order ensure that there is sufficient specialised oral care services to this population. Oral care providers need to have all the necessary expertise and skills to interact effectively with children with SHCNs and their families. Oral care providers should establish and maintain good communication with caregivers and parents of these children and assist them in providing all the required support. Interventions are needed immediately in order to increase the awareness of parents and caregivers regarding the treatment and prevention of oral diseases

5.2 Introduction

Children with special health care needs (SHCNs) are often described as those who suffer from any kind of chronic, sensory, emotional, mental, behavioural, physical or cognitive medical conditions for which routine healthcare is not adequate (20). According to the existing literature, the oral hygiene of children with SHCNs is often poor. The literature also suggests that such children have a higher number of tooth extractions, an increased prevalence of caries, an increased chance of periodontal disease and a lower probability of receiving proper treatment for these oral health issues as compared to children without needs (41,52–54,71–73, 83, 251–253). Accordingly, children with SHCNs may have significant restrictions in oral hygiene performance because of their intellectual, sensory and motor needs, and therefore are more likely to suffer oral health issues than other children (45–47, 138, 254). In addition, these children may also lack a proper understanding of preventive oral health practices (97).

Deterioration of oral health among children with SHCNs can, in part, be attributed to various underlying factors such as enamel irregularities, craniofacial birth defects, impaired salivary function, malocclusion, periodontal disease, and more frequent oral infections (84,290). Additional factors include an over-dependence on a healthcare professional for regular oral hygiene, frequent use of medicines that have high sugar content, preference for foods rich in carbohydrate, oral aversions, inadequate oral cavity care, and a liquid or semi-liquid diet (14).

There has been a rapid growth in the population of people with special or complex needs, and this population usually also experiences significant issues related to oral health care (291). As mentioned above, children with SCHNs have complex oral health needs which may be a result of a lack of professional and timely personal care for the maintenance of oral health, congenital anomalies and the comorbidities that arise from them (292,293). It is important to take an interdisciplinary approach to ensure proper oral care for children with SHCNs (294,295). Not only does this necessitate the need for a team effort by the dental hygienist, dentist and dental assistant, it also requires frequent collaboration with family members and primary health care providers to ensure that proper oral care is delivered to the child (146, 160, 261).

It is important to provide appropriate oral care in order to promote quality of life and good health for everyone, essentially for children with SHCNs (297). While it is widely accepted

that children with SCHNs should achieve equitable oral health through equal access to oral healthcare services, this is not the case all the time (16–18). Unfortunately, significant inequalities with issues related to oral health among children with SHCNs remain. This situation often results in limitations to the activities of daily living of these children (289). A strong correlation between children with SHCNs and poor oral health has been established by many research studies, placing dental care as one of the top unmet needs in these children. There is therefore a need for guiding the much-needed advancements and refinements in oral healthcare for children who have SHCNs (130,301,302).

Improving the oral health of children with SHCNs requires ensuring that they have access to the dental practice and high-quality oral health care (156,303). Refusal or postponement of oral care by the healthcare professional can cause difficulties which can lead to an increase in the cost and need for dental treatment, unnecessary pain, discomfort, and weakened or decreased oral health outcomes (92). It is important to understand the barriers that prevent children with SHCNs from obtaining adequate oral health care in order to be able to design and develop appropriate remedies to these barriers (303). Several research studies have suggested that it is difficult to promote oral healthcare in children who have SHCNs because these children are usually uncooperative. These factors help to explain why oral health is often neglected in children with SHCNs, and also provide a framework for assessing current healthcare practices and care provision.

According to estimates of the World Health Organization, people with disabilities make up approximately 12% of the total population within developing nations and 10% within developed nations (25). In recent decades, Saudi Arabia has experienced rapid development which is reflected in the improved healthcare-related services that are now provided within the country (304). However, there is no accurate or adequate data on the number of children with SHCNs in the country or their medical conditions (304). Many studies carried out in Saudi Arabia have set out to explore or examine specific healthcare needs of these children, however, the majority of studies have either failed to use a uniform definition of disability or remain unpublished (304).

In the Kingdom of Saudi Arabia (KSA) there are two healthcare providers: one is funded by the government while the other requires payment for using the healthcare facilities (private

sector). Accordingly, both Saudi and non-Saudi citizens have the right to equal access to all healthcare, including dental facilities, as asserted by the Saudi Constitution (305). The main body providing free healthcare including oral care services in KSA is The Ministry of Health (MOH). The MOH has its own government budget for the management, coordination and detailing of government policies, health programmes and overseeing the health administration process in the private sector. It is also responsible for implementing health-related policies for both the public and private sector to follow the targets and rules set by the government (306).

According to the Saudi MOH, the overall number of dentists working in KSA is 12,785 of whom around 4,456 work within the public sector with the remainder in the private sector. (MOH, 2019). Saudi Arabia is estimated to have 2.3 dentists per 10,000 residents, substantially fewer than that of neighbouring countries and the UK, which has 5.20 dentists per 10,000 residents (307).

The Saudi government, represented by the MOH, has given healthcare services significant attention, which had led to extensive improvement over the last two decades. Despite these achievements, it has been suggested that numerous difficulties still exist (308). The access of individuals with SHCNs to health care facilities (primary, secondary and tertiary) is still reported as one of the major barriers, with some evidence of a shortage in the number of skilled professionals that can meet the country's general and specialised dental needs (308).

Some authors report that a significant financial burden has been placed on the KSA because it provides free health and dental care to all its citizens through the government funded healthcare system (283). In addition, Saudi citizens do not typically have health insurance (283). These factors, when coupled with a shortage of experienced dentists to treat children with SHCNs, complicated administrative procedures, inadequate training of healthcare professionals and limited resources, can limit access to and delivery of suitable oral health care for this group of children in Saudi Arabia (283). Many research studies have been conducted across the globe to study children with SHCNs and their condition (160, 272, 273). However, relatively little research has been carried out to study children with SHCNs in Saudi Arabia, resulting in a research gap in this area. There is a need to address the lack of research exploring oral health among children with SHCNs (283), not least because of the long-term negative consequences

if care is not provided, but also because there is a shared responsibility between healthcare workers and parents towards children with SCHNs and their families.

Oral health is a vital aspect of general health, and in order to maintain overall health, it is important to consider maintaining good oral health. Dental care constitutes all activities that help an individual to access, achieve and continue to achieve the required or optimal dental health (311). These activities include professional dental services, oral hygiene procedures, and any activity that may help maintain functional, aesthetic and healthy teeth and gums. However, relatively few studies have been carried out to explore this issue from the perspective of the parents or primary caregivers of children with SHCNs (312).

Parents and caregivers of children with SHCNs have a particularly important role to play as they are often primarily responsible for oral hygiene behaviour within the home and access to oral care services for their children (313). Many researchers have argued that the involvement of caregivers or parents is necessary for children with SCHNs as these children require support and help to carry out their day-to-day tasks (277, 278). However, the experience of having a child with SCHNs often intensifies the challenges of parenthood (316). Parents of children with SHCNs experience many pressures which are specific to the condition of their child. Some of the key stressors for caregivers or parents of children with SCHNs documented in the literature include difficulty adjusting to or even accepting the needs of their child, limited information about the health of their child, financial demands for necessary healthcare, and time management conflicts (134,316–318).

The attitudes and beliefs of parents towards oral health impact how they provide oral health care for their children. Further, parents from different cultures have different behaviours; they are mainly guided by the value systems and general cultural norms (319). Therefore, parental value systems, as well as practices, are among some of the key factors which mediate the impacts of culture on the oral health of children, especially the ones with SHCNs (320). However, little is known about the personal beliefs of parents and the way they practice oral health care for children with SHCNs. Exploration and analysis of the perceptions of parents through qualitative research may shed light on the strengths and weaknesses in current oral healthcare services, and the value that parents place on oral health care.

Qualitative research provides a key perspective in exploring as well as examining perceptions and views for oral health, particularly in a group as complex and diverse as children with SHCNs. Limited qualitative research exists in dentistry, compared to medicine for example. Moreover, qualitative research with caregivers and parents of children with SHCNs in dental care is even more limited (321). An understanding of the perceptions of parents and caregivers regarding the status of oral health among their children, the use of preventative measures and awareness of dental problems is essential for oral care providers, especially those who may have to treat children with SHCNs and their families. This is because perceptions of caregivers and parents can impact treatment choices and preventative care (322). Qualitative research methods can serve as a strong research tool to help gain a deeper understanding and knowledge of attitudes and perceptions (286, 287). Despite the clear benefits of such an approach, the use of qualitative research methods in exploring oral health needs remains limited (321).

More and more people, including health professionals, are now paying increasing attention to the importance of oral health, but relatively little attention has been paid to oral health among children with SHCNs. It is vital to conduct in-depth research in this area as children with SHCNs have been found to experience far more oral health issues as compared to children without SHCNs (311). Understanding the parental or caregiver perceptions and the experiences of children with SHCNs will elicit a deeper understanding of oral care delivery, oral health practices and provision of care among children with SHCNs. This knowledge will facilitate an understanding of the principal challenges of improving oral care among children with SCHNs with a view to future intervention. The strengths of qualitative methods will explore these areas and understand how parents and caregivers of children with SCHNs experience oral care for their children every day.

This research is a primary investigation that aimed to focus on assessing the perceptions of parents of children with SHCNs with respect to the oral care of their child. The experiences and perceptions of oral care may be different in significant ways from those believed or perceived by policymakers and healthcare professionals. Children with SHCNs have many different medical conditions and their experiences with oral care can vary in substantial ways. Understanding the perceptions of parents is important to developing healthcare interventions as well as facilitating efforts to reducing barriers and initiating effective patient-centred care (325).

Interviewing parents can provide in-depth, diverse information about the oral healthcare experiences of their children. The use of this information to alleviate some of the obstacles faced by children with SHCNs has the potential for enhancing care significantly, similar to that suggested by Lewis et al. (2005) (58). Further, this information may help to determine priorities for developing efforts for addressing this population's needs as relating to oral healthcare and develop new procedures and methods to provide appropriate oral care and develop long-lasting cooperation between parents and oral care providers.

5.3 Aims of the Study

This study aims to explore the perceptions as well as the experiences of the caregivers and parents related to oral care delivery, oral health practice and provision of care for children with SHCNs. This study was reported according to COREQ checklist (326).

The main research questions that this study was designed to explore from the perspectives of caregivers and parents were:

- What are parental perceptions of the oral care that their children receive?
- How are the specific oral health requirements of their child(ren) being supported by their dentist or oral health care provider?
- What issues do children encounter when they access or receive oral care?
- How do parents perceive their role and involvement in the oral care provided to their child(ren)?

The views and perceptions of the caregivers and parents of children with SHCNs were explored qualitatively. The qualitative research method was chosen to describe the factors that influence the experience of oral care.

5.4 Methodology

Study design

The overall aim of this research was to explore the perceptions and experiences of the caregivers in relation to the provision of oral care for children with SHCNs. This was a qualitative study. Semi-structured interview were conducted to explore the research question and allow for unexpected themes and information to arise (327). The experiences of the caregivers and parents can be effectively understood through the information achieved from the qualitative studies by describing those experiences properly (328). It has been long argued by researchers that the perceptions of others can be best understood through the interview method, a method to generate data that can provide a deep insight into the experiences of people (299, 300).

The interview research method can help investigate and explore beliefs, experiences, views and motivations of people on certain issues (331). This has been regarded as similar to a conversation with a purpose; the purpose here is to explore and examine the research question as well as the topics relevant to it along with allowing unexpected information and themes to come up in the process (295, 302). This method was considered to be an appropriate method to explore the perceptions and experiences of the target group with the oral health behaviours of their children.

Theoretical framework

Thematic analysis was used in this study for identifying, analysing and reporting patterns (themes) within data (333). Thematic analysis is defined as *"a common general approach to analysing qualitative data that does not rely on the specialized procedures of other means of analysis such as grounded theory methodology, discourse analysis, and semiotic analysis."* (334). This approach allows for a large volume of information to be summarised and categorised into significant topics or themes and is considered as "a flexible and useful research tool, which can potentially provide a rich and detailed, yet complex account of data" (333). We considered thematic analysis as an appropriate method for the analysis of the interview

data and used the six stages of analysis provided by Braun and Clarke (2006) to generate the relevant themes (333).

Participant selection

Sampling

The purposive strategy of sampling was used for selecting parents and caregivers whose experiences and perceptions would be relevant to the aims and questions of the research (291, 292). This sampling method aims to identify as well as select people who have varying opinions and experiences that will allow them to provide appropriate answers to the research questions. An effective strategy for purposive sampling should result data saturation when data gathering yields no new data that cannot be assimilated into the themes that have already been developed (293, 294). Data collection continued until saturation was achieved.

Recruitment (Method of approach)

Recruitment took place in the capital city of Saudi Arabia - Riyadh. It was decided that the most convenient source of participants was parents of Special Needs Schools in the city. The Ministry of Education is primarily responsible for taking care of all the education systems within the country. The Ministry is also responsible for the education of children with SHCNs (283).

The recruitment process was carried out by the participating school headteachers that had agreed to take part in the study. All physical and electronic study materials were given to the school directors. There was no face-to-face attempt to interview potential participants (parents) nor to encourage them to take part in the study. When a parent expressed their interest in the study by contacting the main researcher, the researcher enquired as to the child's age and needs in order to confirm eligibility.

Sample size

In qualitative research, there are no rules related to the sample size according to Patton (2002). The sample size depends on the purpose of the researcher, what the researcher wants to know, what will be useful and what is at stake. An initial sample size of 12 to 20 was proposed, with a view that data collection would continue until saturation.

Exploration of the answers to the research questions will help to generate comprehensive information that will ultimately help identify and understand the explanatory themes that can be used for understanding the views or perspectives of the parents. For this purpose, semi-structured interviews were selected because these interviews are suitable for open-ended questions and small sample sizes (332).

Non-participation

Eight primary special needs schools were selected at random and approached to participate in the research; four schools agreed to participate.

Setting

Data collection setting

It has been challenging to conduct research during the COVID-19 pandemic, especially when it comes to data collection. It was important to adapt to the restrictions and to move away from traditional methods of gathering data. It had also become important to adapt to the quarantine rules put in place by governments across different countries. Hence, adaptation in the process of data gathering during the ingoing pandemic was inevitable. Telephone and videoconferencing can be enough to gather data that is live and real-time, yet remote. These methods allow two or more individuals to communicate live using audio and video, no matter which part of the world they are in (339). Therefore, the in-depth interviews were carried out through phone or video-conferencing tools, instead of traditional face-to-face interviews in order to abide by the university guidance and the rules implemented by the local governments. The interviews were carried out by the primary researcher who is a male PhD student with a background in oral health and had training in qualitative research during his studies at the university.

Eligibility

Participants were intentionally selected so that there could be the greatest variation with regards to the topic guide (340). Through the use of this strategy, the researcher was able to identify common patterns that existed in the answers of the participants with the greatest differences in variables that may impact the target group's oral health.

The inclusion criteria were:

- Parents or caregivers of a child between the age of 7 to 11 years old attending special needs education schools in Riyadh, Saudi Arabia
- Parents or caregivers of a child with mild/moderate special healthcare needs
- Parent/carer that agrees to participate in the studies and has provided a consent form
- Parent/carer who agrees to be audio recorded

Parents and caregivers were intentionally selected based on their child's age to obtain a balance across the younger and older age groups (grades one to three (7 to 9 years) and four and five (10 to 11 years) to reflect differences in oral self-care abilities of the children). Only children with mild to moderate special healthcare needs were included in this study. As the main focus of this research was on children who can be managed in a general dental clinic, children with severe or multiple disabilities or needs who were unable to attend a special needs school or primary care unit due to their severe developmental delay or additional medical or behavioural comorbidity were ineligible for inclusion in the study.

Data collection

Interview guide

After a thorough literature review, the researcher developed a semi-structured interview/topic guide which was then peer reviewed (Appendix 4). Similar to qualitative descriptive approaches, this semi-structured interview comprised questions that were kept open-ended on purpose - so that discussion can be prompted and natural answers could be elicited from the interview participants (341). These questions were piloted and examined with two caregivers/parents in order to make sure that all the questions were easy to understand.

There was an initial focus on broad aspects of oral health such as the importance of oral health and the general health of the child in order to set the context and facilitate a more in-depth discussion of the perception and experience of the caregivers or parents with the oral care delivered to their children.

Interview process - Audio recording

Each interview was recorded and then transcribed *verbatim* by the main researcher. As the interviews were carried out in Arabic, the primary researcher translated each one into English for consideration by other members of the research team. A sub-sample of interviews was taken and back translated into the original language in order to validate the process of translation and check its accuracy (342). No major differences were revealed upon comparison of the original and back-translated transcripts.

Transcription

Each interview was transcribed immediately after the interview was conducted. The accuracy of each transcription was then carefully reviewed (Appendix 5).

Duration

The planned duration of each interviews was 30 to 45 minutes.

Data saturation

We planned to recruit participants until data saturation was reached.

Data analysis

The transcripts were read in their entirety many times by the main author so that their meaning could be fully understood. When the text was being read, important statements were extracted, and each statement was labelled with a unique code and examined carefully. A subsample of transcripts was shared with other members of the research team. Coding and theme generation were carried out independently and the findings were discussed and compared with the research team in virtual meetings. All the codes or statements that were similar and created a pattern were assimilated and summarised into common themes. The research team members continued to compare, categorise and re-categorise codes during subsequent virtual meetings for comprehensive data analysis (Table 11) (Appendix 5). We did not return transcripts to participants for checking / comment, and no participants provided feedback on the findings.

Phase	Description of the process
1. Familiarising yourself with your data:	Transcribing data (if necessary), reading and rereading the data, noting down initial ideas.
2. Generating initial codes:	Coding interesting features of the data in a systematic fashion across the entire data set, collating data relevant to each code.
3. Searching for themes:	Collating codes into potential themes, gathering all data relevant to each potential theme.
4. Reviewing themes:	Checking in the themes work in relation to the coded extracts (Level 1) and the entire data set (Level 2), generating a thematic 'map' of the analysis.
5. Defining and naming themes:	Ongoing analysis to refine the specifics of each theme, and the overall story the analysis tells; generating clear definitions and names for each theme.
6. Producing the report:	The final opportunity for analysis. Selection of vivid, compelling extract examples, final analysis of selected extracts, relating back of the analysis to the research question and literature, producing a scholarly report of the analysis.

Table 11: Phases of Thematic Analysis (333)

Ethical considerations

All the interviews were conducted taking into consideration the ethical framework granted by the University of Manchester (13/03/2020; Ref: 2020-8323-1362) (Appendix 6). This ethical framework guarantees each participant's willing acceptance, anonymity of each interviewee, the possibility for each participant to seek information or to consult the data, and the confidentiality of each interviewee. All participants were informed through the participant

information sheet that the interviews were being recorded using a digital voice recorder that are stored safely and only accessible by the researcher or supervisory team.

5.5 Results

A total of 12 parents of children with SHCNs that met the inclusion criteria of the study were interviewed. Table 8 presents the characteristics of the sample. No medical reports or diagnostic details of the children were requested from the parent / caregiver participants, however, parents reported that eight children had Autism and four had Downs Syndrome (Table 12).

Parent	Gender	Occupation	Age of child	Gender of child	Special needs	Comorbidities
PP1	Male	Teacher	11	Girl	Autism	ADHD*
PP2	Male	Middle school principal	11	Boy	Autism	None reported
PP3	Female	Private sector	8	Boy	Downs syndrome	None reported
PP4	Female	Housewife	9	Girl	Autism	AD
PP5	Male	Military	10	Boy	Autism	Sleep disorder
PP6	Female	Teacher	8	Girl	Autism	None reported
PP7	Female	Teacher	10	Girl	Autism	None reported
PP8	Male	Private sector	7	Boy	Autism	None reported
PP9	Male	Private health sector	11	Girl	Downs syndrome	None reported
PP10	Female	Teacher	11	Girl	Autism	ADHD
PP11	Male	Teacher	9	Boy	Downs syndrome	None reported
PP12	Female	Electrical engineer	8	Boy	Downs syndrome	None reported

Table 12: Participant demographics

*AD, Anxiety Disorder; ADHD, Attention Deficit Hyperactivity Disorder

Before presenting the themes, it is helpful to restate the research questions that were addressed in this study:

- What are parental perceptions of the oral care that their children receive?
- How are the specific oral health requirements of their child(ren) being supported by their dentist or oral health care provider?
- What issues do children encounter when they access or receive oral care?
- How do parents perceive their role and involvement in the oral care provided to their child(ren)?

Themes and sub-themes emerging from the data included:

1. Perception of oral health
2. Parents' role - oral hygiene, communication
3. Oral care experiences relating to the dental appointment - specialist care, use of general anaesthesia (GA), routine dental visits, children's behavioural issues, lack of knowledge/understanding of SHCNs by the treating dentist
4. Issues with current oral care - waiting time to receive an appointment, lack of continuity/referral, lack of information/support
5. Parental views of the ideal practice

5.5.1 Perception of oral health

This theme refers to parental knowledge and perceptions of oral health. Parental beliefs and practices of oral health influence the oral health behaviours which they initiate for their children. It was generally agreed that keeping their children's teeth clean and avoiding any signs of dental disease were the general conception of oral health of interviewed parents. This was clearly articulated when the participant PP12 highlighted that

> *"of course, it's important to look after them, especially for children with additional needs as their teeth and gums can get bad if not looked after"* (PP12).

Several participants commented on how having poor oral health could impact general health. It is unclear whether this belief was because participants were aware of the connection, or whether it seemed that oral health was an important subject for them

> *".. it is essential and part of the body and we should always pay attention to it"* (PP2).

Poor oral health was perceived by some parents to cause difficulties with their children's diet and speech. PP9 stressed that

> *"if there is a problem in the mouth, the child will not be able to eat or speak well, and that's why it's really important that the mouth and the teeth should be cleaned and looked after which depends on brushing, going to the dentist and follow-ups"* (PP9).

Some participants seemed to believe that their children had bad teeth and that was linked to their children's disabilities or healthcare needs:

> *"it's important especially with children with Down's syndrome…because their teeth had many issues…"* (PP11).

Parents also acknowledged that maintaining oral health was not easy for them, knowing their children's disabilities or healthcare needs. PP7 stated:

"Of course, it is important to have clean teeth, and to keep them clean all the time. We try our best with our children, but it is hard especially with my daughter…" (PP7).

Most participants had a good understanding of oral health as they linked it to the absence of dental disease. Parents generally spoke about the importance of oral health and preventing the need for dental treatment with the associated pain and discomfort. This matter was clearly articulated among the participants and they felt they needed to pay more attention to oral health knowing their children's vulnerability.

5.5.2 Parents' role

The participants typically stated that mothers are mostly responsible for the oral health of their children at home. The mother PP6 said:

"most of the time I am the one who helps my daughter with brushing" (PP6).

The same point was highlighted by the mother PP3, who reported

"actually, I am the one who cares for my child's teeth, as I am always at home; I try to follow up with brushing and looking after his oral health" (PP3).

Most of the participants spoke about the lack of involvement of fathers in oral care at home. The father PP11 mentioned that his wife is the one who helps their son with brushing and looking after his teeth. PP8 pointed out that

"regarding brushing, we always help our son. I mean his mother mainly does that; she is the one who looks after him. However, as our son got older, he became somehow independent in brushing his teeth. Thus, my wife doesn't help him very much" (PP8).

Making decisions about dental care for the child was largely seen as the mother's responsibility where PP1 reported that parents are not sharing this role equally.

".... her mother, because of my occupation, my wife, and she is trying to keep up .... you know with brushing and if she feels pain or if she needs to go to the dentist" (PP1).

In this regard, the participant PP5 reported that

> *"My wife is the one who is taking care of my son's teeth, to be honest, most of us [men], we don't care that much"* (PP5).

It appears that most fathers are absolving themselves of any responsibility for oral care at home and leaving this matter to their spouse. It seems that mothers take responsibility for oral care and for the implementation of preventive approaches to dental care in addition to the general demands of childrearing.

5.5.2.1 Oral hygiene (resistance to brushing)

All participants discussed the importance of child oral hygiene. The majority of participants clearly indicated that there was some resistance to brushing by the children with SHCNs, especially when brushing was first introduced. PP1 stated:

> *"When we first gave our daughter the toothbrush, we recognized that she had difficulty cleaning her teeth on her own. One day, she broke the toothbrush and refused to use it"* (PP1).

Similarly, PP4 discussed her struggles to help her daughter brush her teeth as she does not like using a toothbrush. PP4 also added that her daughter sometimes pushes her if she tries to clean her teeth. Participant PP8 also shared his experience with his son regarding toothbrushing, highlighting his child's resistance to brushing and their approach to overcoming this through sub-optimal brushing practice:

> *"we are not doing a good job with brushing to be honest with you, sometimes our son throws up when we ask him to brush his teeth, he even doesn't like the taste of the toothpaste, so we try to brush his teeth without any toothpaste"* (PP8).

This reported dislike for toothpaste was not an isolated case, with participant PP11 stating:

"our son refused to let us brush his teeth as he was afraid, he didn't like the taste of the toothpaste…but now I think he is doing much better" (PP11).

Self-cleaning of the child's mouth was sometimes seen as a problem. Some parents acknowledged that their children were not brushing their teeth and expressed a need for additional support and education to address the difficulties they encountered.

"to be honest she is not brushing…. I'm struggling with her brushing…she doesn't want to do it and I need help" (PP4).

Oral hygiene represents the most important practice of oral health according to the participants. Parents expressed frustration at their attempts to care for their children's teeth because of resistance from the child, lack of co-operation, or lack of knowledge about how to brush correctly. Some parents acknowledged that tooth brushing is difficult and that they need help and support. It also appears that parents, mainly the mothers, are often the ones who brush their children's teeth.

5.5.2.2 Communication issues

This theme refers to the difficulties in communication between children and their parents and between children and their dentists. Parents expressed frustration with their efforts to communicate with their children during home care and dental visits. Some participants acknowledged that their children had difficulty in expressing the source of their pain. PP3 highlighted that

"It is hard for our son to express himself, so we sometimes struggle to understand the source of the pain or which tooth is hurting him; likewise, when we visit the dentist, he [the son] finds it hard to communicate" (PP3).

Along the same lines, PP5 declared that

"most autistic children have an issue with speech and communication" (PP5).

Some parents mentioned that it can be hard to differentiate between toothache and behavioural issues as their children are unable to communicate with them. PP12 pointed out that her son sometimes touches his teeth to show that it is hurting him. This was raised by another mother, PP10, who reported that whenever her daughter has some pain in her teeth, she starts pointing to her teeth, so they understand that she feels toothache. The same point was stressed by PP1 who said,

> *"My daughter sometimes starts crying because of pain, but we do not know if the pain is in her teeth or somewhere else…even if we knew the source of pain, we find it very hard to identify which tooth is hurting her"* (PP1).

Many parents reported a struggle to achieve effective communication between their children and dentist during treatment. Parents felt responsible to communicate on behalf of their children and stated that the dentist did not understand or reach out to their children during treatment:

> *"If they [dentists] can sit with my son and try to communicate with him from the start is really important… I know it's not easy…"* (PP3).

> *"But to reach out to her and ask her…. there is no communication… I always try to do it by myself…"* (PP6).

Parents seemed to struggle to achieve effective communication with their children both at home and at the dental office. The communication deficits were reported to result in limited daily oral care and restricted access to dental care for these children.

> *"Sometimes it is really hard to know if my daughter is in pain…or if she has swelling in her mouth…because she doesn't let us see or brush her teeth … and we don't know what to do…"* (PP4)

5.5.3 Oral care experiences relating to dental visits

5.5.3.1 Lack of specialist care

Lack of specialist care is one of the major themes arising from the data. With regard to dental attendance, one of the biggest challenges for participants seemed to be finding a dentist willing to treat their children. PP7 experienced difficulty and stated that

> *"I wish we could find a specialist dentist for my daughter, but it is extremely hard to find one"* (PP7).

The same issue was highlighted by PP1 who mentioned

> *"we hope that at least there is a clinic with a dentist who is a specialist with these children…. I mean, we find it hard to find a specialist to deal with our daughter"* (PP1).

Parents reported perceived shortages of specialist dentists who are qualified to deliver the appropriate dental care for their children. PP3 stressed that

> *"I think having many specialist dentists who know how to handle our children are important…. if we have many dentists this will be better for our children"* (PP3).

PP1 also added that many parents who have autistic children complain and suffer from the lack of specialist dentists in the area. PP1 stressed that

> *"I mean, all parents who have an autistic child are suffering about the idea of having a dentist that can understand the condition of their son or daughter…. some physicians understand my daughter's condition especially paediatricians who actually understand the state of autism, and they are interested in my child health, but dentists, they have little background and avoid treating such children"* (PP1).

The father PP2 also stated that dentists needed specialist training on how to deal with special needs children in order to help them.

> *"I think dentists should be specialised with these children and have the knowledge and ability to treat with them with open arms…"* (PP2).

PP4 stated that one dentist was very angry when her daughter showed some resistance in the clinic. Furthermore, PP4 mentioned that most dentists have no idea how to deal with children with SHCNs and as result the family are always looking for suitable care provision. PP9 said that some dentists even refuse to see his daughter and that he struggles to find specialist dentists:

> *"some dentists refuse to see these children…and they don't have the patience to treat them…so we have to find another dentist…"* (PP9).

The search for a dentist capable of delivering oral care was perceived as stressful and hard. Some parents shared their experiences and reported their concerns regarding their inability to find specialist dentist care for their children:

> *"and if she [the daughter] tells us about a problem in her mouth we always fear because we know it's hard to find someone who will treat her and understand her needs"* (PP1).

Similarly, PP11 reported

> *"it was hard for us to find a dentist willing to treat my son and understand his condition"* (PP11).

It seems unclear why general dental practices were unable to provide oral care for participants' children. Lack of available specialist care was reported by parents to cause them considerable distress. Dentist rejection and parental fear of inability to find a dentist that can deliver appropriate dental treatment are some of the experiences and concerns raised by the participants in this theme.

5.5.3.2 The fear of using of General Anaesthesia (GA)

Another major theme generated in the data is the use of general anaesthesia (GA). Most parents responded with fear, worry and concern when they first heard that their child needed to undergo GA for dental treatment. Parents were uncomfortable when dentists said that they could only treat their children under GA.

"The dentist in one hospital told us that they can do the treatment only under general anaesthesia; they immediately asked for that without trying any other sort of treatment, for me as a mum, it is really hard, and I feel unhappy about it" (PP6).

In the same vein, PP8 indicated that

"I am very concerned about the use of general anaesthesia" (PP8).

Parents expressed their concern that dentists are not making sufficient efforts to provide oral care before resorting to the use of GA. Parents seemed to be worried about their children, particularly if they had gone under GA several times. PP1 reported that

"most of the dentists will only examine my daughter under general anaesthesia. Only few dentists try to treat her without general anaesthesia, but others did not and prefer to put her in a complete sleep. My daughter has been put under general anaesthesia five times before… and we actually are concerned about that" (PP1).

Most parents report additional stress about the need to go under GA for treating a single tooth. PP8 also expressed his concerns about the use of GA and the lack of available options:

"I fear that my son will not be treated unless he goes under general anaesthesia to treat only one tooth" (PP8).

Parents appeared to be aware of the complications of GA. Parents were keen to avoid dental treatment under GA and believed that alternative methods of behaviour management were not always attempted before resorting to GA. Experiencing GA was distressing for parents and did not seem to reduce parents' fears. Some parents even speculated that they might avoid or delay future dental visits as treatment often required a GA.

5.5.3.3 Routine dental visits

This theme was generated from the interviews when the participants were asked about their experiences of visiting the dentist. It was clear that most participants visited the dentist practice

only when their children were in pain. In other words, they did not follow routine, regular dentist visits.

> *"Unfortunately, we visit dentists only if she is ill or if I notice that her teeth are getting bad"* (PP10).

Some parents described visiting the dentist as a tense trip that was only made when they had to. PP1 explained that

> *"we only visit the dentist when my daughter has pain, when she complains about her teeth, we go, of course we try to go often…. but it is not easy for us as I told you"* (PP1).

Some parents reported avoiding taking their children for dental care due to previous negative experiences:

> *"We actually try not to visit dentists because we do not want our daughter to suffer or be mistreated. She is sensitive and she gets upset easily"* (PP7).

Likewise, PP2 explained that

> *"yes, we usually do not go for check-ups, we only visit the dentist if my son says, 'I have pain', so we try to go"* (PP2).

One participant reported that they usually go to a private clinic as they find it hard to receive dental care without going for GA in public clinics. Public sector dentists appear to be unwilling to treat Children with SHCNs without use of GA:

> *"We always go to private clinic… the dentist in the public clinic always ask to use general anaesthesia to treat my daughter"* (PP1).

Many parents reported that they visited public clinics but often had concerns about accessing public clinics for urgent care. Private clinics were perceived as safer, more comfortable and more accessible for their children. Children's experiences were linked to some of the parents'

personal experiences and reasons for making choices as to which service to attend. PP7 highlighted that

> "*I believe it is hard to get an appointment in public clinics, so we always try to go to private clinics, my husband and I prefer to go to private clinics even for our own appointments"* (PP7).

The reasons for limited attendance in dental clinics was a recurring issue raised by most of the participants. Reasons for limited attendance were linked to often unpleasant treatment, negative past experiences, and a belief that going to the dentist was something largely to be avoided. Most parents attend a dental practice only when their children were in pain and as a last resort. Parents attended private clinics, which appeared to provide urgent and accessible care when they need it. Some parents appeared to be unaware of the consequences of irregular attendance in receiving dental care and that it could result in more problems.

5.5.3.4 Behavioural issues

This theme is related to the preceding theme of dental visits as some participants feel embarrassment about the behaviour of their children when they visit the dentist. Interviewed parents recognised that behavioural issues could limit dental treatment for their children. PP7 pointed out that

> *"I mean it is hard when she has a filling or something else, because she moves a lot and I have to hold her and she doesn't like that"*(PP7).

> *"My daughter sometimes cries with pain, but it is not easy for us to know the source of the pain. Especially if she has toothache, it is very hard even for dentists to know which tooth is hurting her"*(PP1).

One parent reported a strong stigma concerning their child's behaviour during the dental visit, especially in the waiting area. Behavioural issues seemed to affect her choice as to where to pursue dental care for her child. PP7 stated that

"There are not too many people at the private clinic, so my daughter will not get afraid…. and I will not be embarrassed of her behaviour in front of others"(PP4).

Whilst most parents sought dental care despite of behavioural issues, some parents acknowledge that limited attendance for dental care was linked to their own fear of the dentist and their inability to manage the behaviour of their children.

"I think our fear of the dentist…how is he going to deal with my daughter? [Does this] limit our visits? … I believe so …like my daughter is afraid of others and we need the dentist to be nice and understanding of her condition …" (PP7).

Along the same lines, two parents were keen to avoid dental care because of previous negative experiences:

"*my son does not like to see doctors, especially dentists. It started with him when he was 9 years old, the dentist hurt him while giving him the needle, so now when I tell him about going to the dentist, he refuses permanently and is terrified and does not want to go"*(PP2).

"[We do not attend regularly] because we are embarrassed of my daughter actions and behaviour when we get there…." (PP4).

Behaviour challenges at dental appointments were reported by some of the parents where noise and sound caused anxiety and distress for their children. PP3 stressed that

"my son has some fear...once when he sat at the dental chair it was fine…no problem, until he heard the sound of the drill...I held my son's hands, and the nurse held his feet…it is really hard" (PP3).

One parent shared her experiences of joy and relief of finding a dentist that was capable of managing her child's behaviour.

"I'm happy with that…because her current dentist knows how to approach her without causing her any fear…indeed we faced many issues before …. because no one had

understood my daughter's condition. The most important thing for us is that she is happy now…." (PP6).

All the interviewed participants showed a deep concern about their child's behaviour. Most of the parents recognised that behavioural issues limited their dental attendance. Some parents believed that their child's behavioural problems would be unmanageable and as a result limited access to care. Negative experiences were also reported to result in irregular attendance. Stigma was described where parents felt unable to control their children when they exhibited undesirable behaviours. Some of the parents also believed that dentists were capable of managing their children but were unwilling to accept the inconvenience.

5.5.3.5 Lack of knowledge/understanding (Dentists' ability to manage children)

A perceived lack of competence of dental professionals was described by all the parents as a major barrier to receiving dental care. Some participants indicated that their children needed specific considerations regarding their oral care:

> *"once the dentists understand my daughter's condition, or she has difficulty communicating with him or her, their attitude changed immediately...."* (PP1).

> *"the first time the dentist did not do a good job…he was really bad with my son…."* (PP8).

All the participants were undoubtedly invested in the qualities of oral care they wanted from the dentist. A child with special needs requires constant care and support, which results in excessive stress and strain for the parents:

> *"Our first experience was not good …my daughter had a bad reaction because of the first dentist…she was saying why did he refuse to treat me…. why is he dealing with us in a bad way…? he just said no and referred us…this was shocking of us…he didn't even try to help us or even explain to us why he cannot treat my daughter"* (PP6).

There was considerable anxiety among some of the participants concerning seeking care, specifically being able to find a dentist who was able to manage their children. Even pursuing

dental care in a private clinic did not translate into improved dental care for some of the parents. PP11 stated that

> *"even some private clinics say that they have a specialist for children but sometimes that's not true"* (PP11).

Even more distressing to some of the participants was the feeling that a dentist had misrepresented themselves as a specialist but who was not:

> *"When I come to the front desk and get in the clinic…. I find that he is a general practitioner and just wants to complete the treatment for the money"* (PP3).

Some of the parents faced many challenges in deciding what was best for their children. The dentist appeared to fail to give the parents proper directions. Parents appeared frustrated that dentists were not invested in their child's oral care. The point of struggle was described by participant PP12 who said

> *"my son had a swelling in one of his teeth….and the dentist did not try to examine him or see what the problem is…. he did not try to do anything…. he just gave us antipoetic…."* (PP12).

Lack of knowledge and understanding from dental professionals resulted in treatment rejection, referral or delay of care caused parents' considerable distress. These issues were seen as a sign of the inability of the dentist to deliver adequate oral care. Despite parents visiting private clinics, some dentists showed no interest in treating their children

5.5.4 Existing issues with current oral care

5.5.4.1 Waiting times

All participants indicated that waiting time for treatment was one of the biggest challenges that existed with the current oral care system. Parents reported having to wait for a long time in order to get an appointment. PP11 stated that

"sometimes we wait a long time for an appointment…the first time we waited for about five months…" (PP11).

Some parents felt anxious about seeking dental treatment knowing the lack of services available for their children. One parent reported the waiting time as a painful experience for them especially when their child was in pain.

"…. but sometimes it's not easy…you have to wait…and sometimes you need a referral…. this is hard for us…. especially when my daughter is in pain and we have to wait for a long time…." (PP1).

Waiting time for an appointment was an issue for all the participants. Many parents reported that they would rather pay for private care than wait for appointments in the public clinic. Most participants reported that the main advantage of private dental care was that the waiting times for appointments were a lot shorter compared to those of public clinics.

"Now, I go to the private clinic because we can get appointments straight away and we don't need to wait for a long time, you need to wait for months to get an appointment in the public clinic" (PP3).

"once it took us about five months to get an appointment at the public clinic" (PP10).

For one parent, there was a perception that dentists in a private clinic setting were more pleasant. PP8 stated

"most of the time we go to the private clinic because the dentists treat us in a good way, and we don't need to wait for a long time"(PP8).

Although most of the participants acknowledged that 'waiting time" was an issue with current public care dentistry and tried to seek care in private clinics, this did not necessarily translate into better dental care. Having to wait for an appointment while their child was in pain caused concern to the parents. There was a level of reliance from most of parents in the efficiency of the private clinics, especially when they sought urgent care for their children.

5.5.4.2 Lack of continuity/referral

Another theme emerging from the existing issues with the current oral care was referral. Almost all the participants reported that the dentist seemed reluctant to treat children when they attempted to access and receive dental care, preferring instead to refer onwards. This issue of care appeared to be a key factor behind the dentist's inability to deliver care for their children. PP3 stated that

> *"they referred us from one clinic to another…. until they referred us to the main hospital, they said wait until we call you…until now after more than two years no one contacted me…"* (PP3).

> *"…and some dentist just try for a bit and eventually refer us to a different one"* (PP1).

Even the reliance on private providers appeared not to resolve the lack of continuity in dental care. Referral and refusing to deliver care to their children seemed to cause an extra burden for several parents as they reported their experiences.

> *"…. it's not easy… sometimes you need a referral…. this is hard especially when my son is in pain ..." (PP12).*

> *"I took my daughter once to a clinic…but they just referred us to another place ….and the dentist we saw only examined her and said I cannot help her…. then he transferred us to the main hospital…I mean it is hard to see a lot of dentists…as you know my daughter's condition it is difficult …they [children with needs], should be managed carefully…" (PP6).*

Referrals were also reported by parents to be made by dentists following a poor quality of care. PP12 and PP5 stated that

> *".. when we told the dentist about my son's condition…. he just stopped and gave us medication and referred us to a different dentist"* (PP12)

"one dentist during the appointment said I cannot do anything else for your child …we have to refer him." (PP5).

Referral was almost always blamed on dentists either not being able to handle the behaviour of their children, or because of the dentist's lack of knowledge or inexperience. Parents also seemed confused about the referral process and what to expect, particularly in relation to difficulties around providing dental care for their children.

5.5.4.3 Lack of information/support

A common theme was the frustration expressed by participants regarding the lack of oral health information and support for many preventive oral care measures. Considerable confusion was evident among participants around the importance of fluoride and its role in dental health. Being unable to get clear information and advice on its use in children was apparent. Fluoride and pit and fissure sealants were new concepts for almost all the parents, including one father who reported learning about it from his wife:

"… my wife told me about the fluoride once, but I didn't know, next time I will ask the dentist about fluoride and protective layer, but no one told us about that. Moreover, no one has suggested any toothpaste or toothbrush for my son" (PP5).

"Unfortunately, no one offered us any support or assistance. No one even offered us any additional measures as …. protective layer on the teeth." (PP1).

Similarly, PP1 said that the dental clinics do not provide any sort of advice even for basic aspect oral home care such as toothbrushing. PP11 pointed out that

"…. we just go to the dentist for treatment…. there is no follow-up…. like to see if my son is brushing or having pain….no nothing like that" (PP11).

Some parents reported that they had asked the dentist about brushing and what sort of fluoridated toothpaste they should use and at what age should they start. Unfortunately, they reported that they did not get any advice or support. Some parents declared that their children did not receive any additional measures when they were treated.

"Even some dentists when I asked them about specific information like what kind of toothpaste or toothbrush… I should use for my son …they always said they are the same" (PP3).

"Unfortunately, none [topical fluoride], I have heard of it before form one of my friends and I even asked some private dentists about that, but I got no response" (PP8).

Some parents reported stress during dental appointments managing their children's behaviour and may not have asked for or retained information given to them at that time. One parent reported that one dentist did offer him some help with the brushing.

"… I only remember one dentist who showed us how to brush…only one dentist…" (PP2).

This concern seemed to be even for other children without SHCNs when one parent reported that

"I haven't heard this before…. even I have an older kid, but this is the first time to hear about fluoride and protective layer" (PP12).

Almost all participants reported that the dentist failed to share information such as oral health instructions or show support or give advice during the dental visit via sharing a leaflet or other means of information. Parents were unaware of the importance of fluoride and other preventive measures such as topical fluoride and pit and fissure sealants. This is a highly alarming finding from a clinical perspective knowing that these children are at high-risk of developing dental disease. Parents seemed eager to know about oral hygiene practices, information regarding available options of care and other preventive measures during the interview.

5.5.5 Ideal Dentist practice from parents' view

Parents had numerous suggestions on how the delivery of oral care could be improved. Some parents believed that improving effective communication would be a good start. Parents also expressed a desire that a dentist should know how to manage uncooperative behaviour. Being

warm, friendly and explaining things to these children was considered by some parents as imperative to improving oral care:

> *"If they [the dentist] can sit with my son and try to communicate with him from the start is really important… I know it's not easy but if they try to show him the clinic or bring a tablet [computer] to encourage him… I think this will make some difference"* (PP3).

> *"if they [dentist] could give lessons to the children…show them…get them to talk in the appointment…I think the dentist should spend more time with us…explaining everything..."* (PP7).

> *"…. also, improving communication with these children and easing their fear before anything"* (PP12).

One parent opined that the dentist needed to encourage parents to become more involved in the oral care of their child.

> *".... it's important that they [dentist] ask us to get involved in caring for my daughter's teeth…like that…to say it's important to brush…and it's necessary to come to the appointment for a check-up…it's really important to pay more attention…"* (PP2).

Many issues of relevance to this theme have previously been raised in other themes. The participants were clear about the qualities they wanted from the dentist treating their children. Parents felt that many dentists needed additional training and experience in managing their children. Parents also believe that dentists needed to be sufficiently trained as this would result in increasing their confidence and communication skills with their children. Parents also wanted more specialist dentists to meet their children's needs and to reduce waiting times for an appointment.

> *"I wish that every hospital had a doctor that can give courses in how to deal with autistic children, and children with special needs, how they can handle them in the clinic? What is the best way to deal with them if they can't approach them? …. these things will bring comfort to the parent …."* (PP1).

"It is absolutely necessary to have a dentist for children with special needs because they will treat them with open arms and understand their needs, this is what I want" (PP2).

"I think having many specialists who know how to handle these children are important…. if we have many [specialists] this will be better for our children and also can save time…time is really important for us as parent…" (PP3).

One parent emphasised how important it was to work with children and avoid the use of GA by adapting their methods or techniques.

"I hope that there will be another way to treat autistic children other than general anaesthesia. There must be other techniques or devices that they can use for these children, and how they can accommodate everything around them" (PP1).

Parents believed that several measures should be put in place to improve the provision of oral care for their children. Whilst most of the participants believed that information and support were imperative to improve oral care it was generally felt that dentists should do more to support the caregivers/parents.

"if the dentist is offering support and information to the father and the mother…. this can build a relationship with the dentist and I believe will help these children…" (PP10).

5.6 Discussion

The aim of this research was to examine the perceptions and experiences of parents/caregivers of children between the ages of 7 and 11 years old with SHCNs. Although the findings of this study support previous studies (322,343) that highlight the challenges faced by children with SHCNs when receiving oral care, this study is unique in that it directly explores parents' experiences and perceptions of dental care services, as well as the preventive measures provided to these children in the city of Riyadh, Saudi Arabia. The outcomes of this research will be invaluable for addressing parental perceptions, experiences and concerns regarding oral care.

Parents reported positive attitudes towards the importance of oral health in general, but they acknowledged some difficulties, particularly around maintaining oral health. Several studies have suggested that parents' attitudes and beliefs towards children's oral health can be reflected in the oral health habits of their children (344,345). In addition, oral health behaviours, attitudes and knowledge of caregivers/parents of children with SHCNs can either hinder or facilitate the promotion and provision of oral health care among their children (29). Therefore, one could anticipate a child's risk of oral diseases by looking at the parent's attitudes and beliefs. (346). Brushing their children's teeth and avoiding any signs of pain or discomfort were the general conception of having a healthy mouth. Although it appeared that parents value the importance of oral health for their children, some acknowledged that a child's disruptive behaviour and other priorities in daily routine related to their children's general health can mean that the importance of oral health is given less priority. Behaviours such as toothbrushing and attending dental care may be missed.

The perceptions of mothers of children and adolescents with SHCNs (Down's syndrome) were investigated by Oliveira et al. (2010) in Brazil, to gaining an understanding of oral health as well as the general health of the children. The findings indicated that good oral health is linked to an absence of disease and feelings of wellbeing (343). The authors reported that although mothers believed toothbrushing was essential to oral health, some other issues in daily life were far more important. Most of the participants in the present study indicated that mothers have the main responsibility for oral care at home, which is in accordance with Oliveira et al. (2010) (343).

Oral health in general is significant for all children, but this significance is emphasised for children with SHCNs. Children with disabilities were recognised to receive less oral health care than others (347). Lowe (2013) reported that children with SHCNs visit dental clinics only when they develop severe oral pain or discomfort (348). This was also reflected in the views of the participants of this study, where the majority of parents highlighted the importance of oral health theoretically, but in reality, they were only able to visit a dentist when their child suffered from pain. Furthermore, several qualitative studies indicated that caregivers or parents of children with SHCNs visit dental clinics only when there is an absolute necessity or an emergency that need attending (283,349).

Parents of children with SHCNs are often considered or assumed to be experts in planning their child's care (350). Evidence has indicated that the parents of children with SHCNs have great experience in understanding the needs and behaviours of their children, which is invaluable for clinical decision-making alongside the dental care professional, and also during the dental appointment (351). This is consistent with the findings of this study as parents indicated that their children are usually dependent on them for identifying dental pain. This experience can lead parents to believe that dental professionals lack the necessary expertise to address their children's needs.

Whilst there is a paucity of evidence regarding oral hygiene habits of children with SHCNs while they are at home, there are several reasons to assume that it may be difficult for caregivers to carry out daily tooth brushing for their children (352). Disruptive behaviours and a difficult temperament, which is more common in children with SHCNs, are some added factors that can affect regular oral hygiene (353). Parents in another qualitative study highlighted some challenges in undertaking toothbrushing for children with SHCNs because of their involuntary movements and challenging behaviours (343). Zaihan et al. (2015) reported that daily problems related to tooth brushing were faced by two-third of the caregivers of children with SHCNs. The most common problem reported was "a child turning the head away" (354).

In the present study, behavioural issues were considered to be the biggest obstacle to carrying out oral care at home. Regular brushing was considered by the parents to be difficult to achieve. As discussed, some parents reported that their struggle was due to the sudden movements and noncompliance of their children. In addition, communication issues, such as a lack of speech, were reported by some parents to cause difficulties in understanding their child's needs. For

example, parents were unable to determine the cause of their child's oral pain. One father admitted that he stopped brushing his child's teeth due to his unsettling behaviour.

Fear of the dentist was recognised by parents as an issue that limited their children's regular attendance to dental clinics. This finding is in accordance with another study on caregivers that reported that fear of dentists accounted for non-attendance of clinics for around 39% of CSHCN, with another study noting 53% of caregivers reporting a similar fear among these children (283,355).

A lack of communication or ineffective communication between oral healthcare providers and children with SHCNs in a clinical setting can prove harmful when the child is unable to fully communicate sensations or when a child is scared, resulting in him/her 'acting out' (296,356). It can be challenging for such children to express pain, as they may have developmental impairments and may not be able to communicate properly (357). The importance of communication during oral care as a key to improving access to dental care services was highlighted in another qualitative study that looked at parents' experiences of children with autism in the UK (358).

Many parents were informed by several oral care providers that their children could only receive treatment under general anaesthesia. Greater levels of fear and anxiety were reported among mothers of children with SHCNs as compared to the fathers who took part in the interview process. The perceived need for general anaesthesia as the only means to deliver oral care disquieted interviewed parents. This factor prevented some parents from seeking professional treatment for their children. In accordance with our study, Amin et al. (2006) reported that the various risks that were associated with delivering oral care under GA and the fear of inadequate care for children made this choice of treatment troubling for parents (359). On the contrary, for children without SHCNs, George et al. (2001) reported that the majority of parents reported that the use of GA was a satisfactory approach that had positive outcomes for their children's oral health (360). However, these findings were reported two weeks after the GA by parents of preschool-aged children.

The lack of specialists was unanimously acknowledged as one of the main barriers to receiving oral care. Accessing a specialised oral healthcare service and being able to receive oral care even in private clinics was a concern. Lack of knowledge and expertise were believed to be the key reasons why oral care provider refused to treat children with SHCN. Other studies support

this finding, reporting that parents and caregivers of children with SHCNs have to deal with several challenges such as finding a skilled oral care provider willing to work with their children (108,356). Williams et al. (2015) reported that the most restrictive factor for individuals with SHCNs in the United States was finding an oral care provider who was willing to work with them (361). The unwillingness to treat children with SHCNs can be linked to the insufficient clinical experience, lack of training during dental school and inadequate knowledge of clinicians reported in other studies (107,362). Waldman and Perlman (2006) and Dao et al. (2005) argue that, in addition to educational factors, there are also many non-educational factors including concerns regarding sufficient compensation and special arrangements that can affect the willingness of a dentist to see or treat patients with special healthcare needs (108,113).

Part of the issue with accessing specialised oral care lies with parents' and caregivers' lack of awareness of the existence of appropriate oral care services in their geographical location. Relying on word of mouth when searching for oral care services for their children was reported. The lack of knowledge of various oral care services among the parents of children with SHCNs may be due to a tendency to avoid participating in social life, self-isolation, or avoidance of seeking support (349,361). Parents reported inadequate effort and support from oral care providers during treatment, and that most treatment offered for their children were emergencies or referral care. Similarly, it was reported by Lawrence et al. (2014) that most of the treatments offered by the oral care providers to children with SHCNs were limited to clinical assessments, urgent care and oral hygiene instruction (363). Furthermore, oral care providers giving limited or inadequate information about options of care for children with SHCNs can contribute to the general unawareness of existing oral care services in the area (364).

Parents often reported experiencing stress and frustration when accessing oral care. In addition, high waiting times were a common concern for parents. Repeated referral was a worrying option of care as some parents believed the dentists to be either unable or unwilling to treat their children. Inconsistent dental care and children being referred from one dentist to another resulted in delayed treatment, missed preventive care and ultimately developing or worsening the oral condition of their children.

Lack of effectiveness within the existing care system resulting in a child's referral to other healthcare providers can also be seen in other countries (365). According to Fonseca et al.

(2010), the quality of life and oral health of a child can be compromised in this way (366). Casamassimo (2004) stated that only 10% of providers had administered care to children with SHCNs. Another study reported that individuals with SHCNs were nearly four times more likely to get stressed or frustrated with the oral care provided to them, and approximately three times more likely to report not being cared for properly (12).

However, the perceived inability of oral care providers to treat or manage children with SHCNs can be the result of uncooperative behaviours during treatment (367). As with parents, communication difficulties, lack of collaboration and involuntary movements are some other factors that may result in this perceived uncooperative behaviour among children with SHCNs by caregivers (109). In addition, scarcity and inadequate accessibility to suitable equipment can limit the ability of oral care providers to deliver appropriate oral care and manage children with SHCNs (61,296,367).

Parents felt ill-equipped to provide adequate support for their children. They reported that they lacked sufficient information or the ability to assist their children with oral care tasks such as toothbrushing. Insufficient knowledge of information related to oral health was reported by all participants. A high level of confusion as to the importance of additional support measures that oral care providers can offer, such as applying pit and fissure sealants, and fluoride application, was evident. A similar result was found by a quantitative study that explored parental challenges in relation to the provision of oral healthcare for children with learning disabilities. The authors of this study indicated that parents faced difficulty obtaining relevant information relating to the provision of oral care in the home (368). In another two-phase qualitative and quantitative study in the UK, the authors highlighted that caregivers of adults with Down's Syndrome wished that they had received appropriate and timely oral health information early in their child's life (369). Since children with SHCNs are more prone to dental diseases than others, it is important to reduce this vulnerable population's health disparities by focussing on preventive techniques and measures (370). Parents and caregivers must have access to appropriate instruction on how they can maintain and improve the oral hygiene of the children in their card, regardless of any behavioural difficulties (370).

As a result of interviewing parents and caregivers, there is a clear need for recommending interventions that can help with overcoming access related issues, behaviours management issues, and preventive intervention measures both at home and at dental office for children with

SHCNs. Screening evidence to identify and recommend evidence-based interventions that might help improve oral health experiences and dental status of children with SHCNs seems appropriate to evaluate as next step.

Limitations

Although the qualitative findings of this study shed light on some of the existing issues in the provision of oral care experienced by parents in the city of Riyadh in Saudi Arabia, some limitations must be noted. The inclusion of parents of children with SHCNs was based completely on their children attending a primary school for special needs, and on parents volunteering their child's specific medical needs to the principal researcher. However, we did gather information related to the previous experience at dental clinics and level of communication of the child, which offers some understanding of the child's ability to cope with treatment and the level of severity which might limit the child access to primary care. Furthermore, this information allowed us to draw a firm understanding of the child's condition and whether they were eligible to be included in this study (356).

It should be acknowledged that the children with SHCNs whose experiences have been examined in this study had different needs. Their oral care, as well as their experiences, can be expected to vary on the basis of their needs and the reasons for attending a dental clinic. Moreover, because our research was carried out within the city of Riyadh with only 12 parents of children with SHCNs were interviewed, our results cannot be considered to be representative of all parents of children with SHCNs. Although the selection of targeted schools was random, participants were self-selecting, meaning that the participants in this sample may have similar characteristics. The generalisation of the results of this study is limited. In addition, interviews were carried out in Arabic which were then transcribed and finally translated into English. The translation process may have lost some of the original meaning and is a possible source of experimenter bias.

Additionally, this research reports on the opinions as well as experiences of parents of children with SHCNs, which may be different from the perceptions of the children themselves. However, it is important to bear in mind that these children are incapable of accessing dental services without parental assistance. However, each of the interviews yielded detailed information on the topic of research. The researchers felt that these interviews served as a way

for the parents of children with SHCNs to express themselves, providing them with a chance to present their views as well as their experiences on the oral health of their children. Furthermore, the findings of the study help to provide a better understanding of the experiences of parents of children with SHCNs, all of which can be put to good use in improving the existing provision of oral care and in developing or implementing interventions to improve patient care.

5.7 Conclusion

Many and varied concerns were raised by parents in this research. Issues related to behaviour, the perceived skills and attitudes of dental health professionals, long waiting times, the referral process and failure to provide additional support and information to parents and caregivers were also commented upon by participants. These factors, combined with the current evidence of a shortage of skilled dentists and resources, complicated administrative procedures as well as improper training of professionals, are major obstructions to providing appropriate oral care for Saudi children with SHCNs.

CHAPTER SIX

Addressing the identified barriers regarding the delivery of oral care for children with special healthcare needs (SHCNs): an appraisal of the evidence base

6.1 Abstract

Background: Oral health of children with special healthcare needs (SHCNs) is negatively affected by structural and systemic barriers. These children usually have less access to oral care, a higher number and frequency of dental diseases, and poorer oral hygiene compared to the general population.

Aim: To evaluate the existing evidence base with regard to interventions that aim to overcome key barriers to the delivery of oral care for children with SHCNs.

Methods: Identification of synthesised evidence, using Medline OVID and relevant guideline websites. Relevant evidence was included and appraised using the GRADE approach. A narrative summary of the evidence was presented alongside a discussion of the applicability of the evidence to increase access, behaviour management and preventive measures of children with SHCNs. Implications of the evidence for practice and research are presented.

Results: Five systematic reviews and five guidelines were identified, that assessed interventions to increase access to dental services, behaviour management and preventive measures for children with SHCNs. Potential interventions to overcome barriers to achieving and maintaining good oral health included fluoride application, training and education programmes aimed at both caregivers and dental staff. The strength of the evidence using GRADE in these reviews were mostly from low to very low certainty. The GRADE assessment was not undertaken for many of the guidelines as there is no direct link to the underpinning evidence.

Conclusion: There is limited evidence to support interventions to improve the delivery of oral care for children with SHCNs with the exception of professionally and self-applied fluorides. The certainty of the evidence presented mostly ranged from low to very low. The applicability of the included evidence to Saudi Arabia is unclear. More high-quality evidence and robust guidelines are needed to address the limitations and shortcoming on the delivery of care for this demographic.

6.2 Background

Previous studies have reported that the prevalence of dental caries in children with SHCNs is similar to other children of the same age (371). However, the oral health of children with SHCNs usually deteriorates faster than that of the general population as they grow older. There are fewer restorations, more missing teeth and more untreated dental caries found in children with SHCNs than in the general population (63,292,372). Moreover, a systematic review carried out by Davis and Anders (2010) emphasised that the prevalence of untreated dental caries and periodontal disease is higher among those with SHCNs as compared to the general population (292). Oral health also has a significant impact on the psychological health of an individual. Poor oral health, for example, can result in reduced nutritional intake, impaired social interactions, difficulty in undertaking day to day activities and associated anxiety (316,373).

The implications of poor oral health are substantial, with some evidence reporting the effects of poor oral health among children with SHCNs on their wider health (374). Recent findings indicate that there are existing health inequalities for children with SHCNs (14,136). Assumptions on the oral health status of these children, when analysed based on the existing literature, are difficult to make, with some studies indicating that the oral health status of children with SHCNs is equivalent to or even better than those without SHCNs (375). However, improvement in the health status of these children may be linked to the growing oral health promotion and rising awareness of the importance of dental care and oral health among this population.

Although barriers and access to oral healthcare services is an extensively researched topic, the research focusing on oral health care issues experienced by children with SHCNs is very limited. Depending on the level, as well as type, of disability or need, these children can be wholly dependent on their caregivers and parents for the majority of daily activities, including oral hygiene. Parents and caregivers are usually the ones who make the decisions in health-related matters and therefore they have a crucial role to play in regard to oral health and preventing oral diseases. Ultimately, the perspective of caregivers and parents of children with SHCNs is directly related to the oral health of these children.

The findings in this thesis indicate that the general perception of parents and caregivers is that the current oral care system in Saudi Arabia fails to adequately provide for children with SHCNs. There are many barriers that were discussed when interviewing these parents including access barriers, behavioural barriers, communication difficulties, , a limited number of healthcare specialists and oral health literacy barriers. Standard oral healthcare services available to children without disabilities may not be easily accessed due to the aforementioned barriers. There is, therefore, a need for a more coordinated, collaborative and multidisciplinary approach towards improving the provision of oral care and making oral healthcare services more inclusive. More patient-centred care training for oral care providers, in addition to the provision of needs/disability-friendly staff, equipment, and healthcare facilities and services is needed to treat children with SHCNs properly.

The limited number of local healthcare professionals, along with continued population growth, has led to challenges and difficulties in maintaining health care quality in the country. It is worth stating that almost 78% of dentists in Kingdom of Saudi Arabia (KSA) are foreign nationals with a high turnover rate of staff (376). This has led to the inability of both the healthcare system and the workforce to pay sufficient attention to the promotion of primary preventive healthcare services, preferring to focus more on hospital-based healthcare services (377). Al Asmri et al. (2019) argue that a more strategic approach must be taken to restore and update the current healthcare system and to ensure that the needs of the population are addressed. Furthermore, the authors highlighted concerns regarding access to healthcare in Saudi Arabia in general. While these concerns are directed at the whole healthcare system, they are also directly relevant to the dental health service (377).

6.3 Aim

To evaluate the existing evidence base with regard to interventions that aim to overcome key barriers to the delivery of oral care for children with SHCNs.

6.4 Methods

We selected key barriers identified throughout the thesis concerning the delivery of oral care for children with SHCNs. For each barrier, we undertook a search of the existing literature. The search was undertaken by the main researcher, using MEDLINE Ovid (Appendix 7) and search of relevant guideline websites (e.g., NICE, SDCEP, RSC, BSDH and AAPD). To be included articles had to be published in English from 2000 onwards. Synthesised evidence (systematic reviews, clinical guidelines) was the focus of the searches, with the emphasis placed on the most recent, high quality publications. It was not the purpose of this chapter to undertake a systematic review of all relevant research evidence but to identify synthesised evidence that was most useful for informing practice/service delivery with regard to access, behaviour management and preventive measures.

The overall body of evidence in the identified publications to support strategies for overcoming identified barriers was assessed using GRADE (Grading of Recommendations, Assessment, Development and Evaluations) (378). The assessment was undertaken by the main researcher and the findings discussed with the research team. Where findings differed across the identified evidence, these discrepancies and potential causes were discussed and summarized as narrative. We categorised the certainty of the evidence, as "high, moderate, low or very low". GRADE requires the assessment of five key domains for each outcome evaluated; Risk of bias in the included studies; Inconsistency across the findings of the included studies; Indirectness, or applicability of the evidence to the question being asked; Imprecision of the findings and Publication bias.

We reviewed the evidence focused on published systematic reviews and guidelines to report on facilitators to increase access to dental care services, interventions with the aim of improving behaviour challenges both at home and in clinic and preventive measures aimed at improving oral health for children with SHCNs. We targeted any intervention that aimed to improve the oral health and help in increase favourable behaviour among children with SHCNs. We considered any evidence of interventions delivered at home, at school, at hospital or in a dental setting; we also included interventions aimed at policy level as well as individual level. The intervention could be provided by oral health practitioners / providers, parents, through community or government. The primary outcome of interest in this study is the improvement in oral health for children with SHCNs.

The inclusion criteria of this review were:

- Systematics review or guidelines focusing on children with SHCNs in paediatric Dentistry providing evidence regarding:
    - Access to dental services
    - Behaviour management
    - Preventive measures

- Published in English
- Published 2000 onwards

6.5 Results

The total number of records identified was 1277. Following removal of duplicates, 189 records remained. After screening the titles and abstracts of each article, the number of potentially relevant articles was reduced to 83. Screening the full text of the remaining records inclusion criteria, the final number publications to be included was 10: 5 systematic reviews and 5 guidelines (Figure 4: PRISMA flow chart).

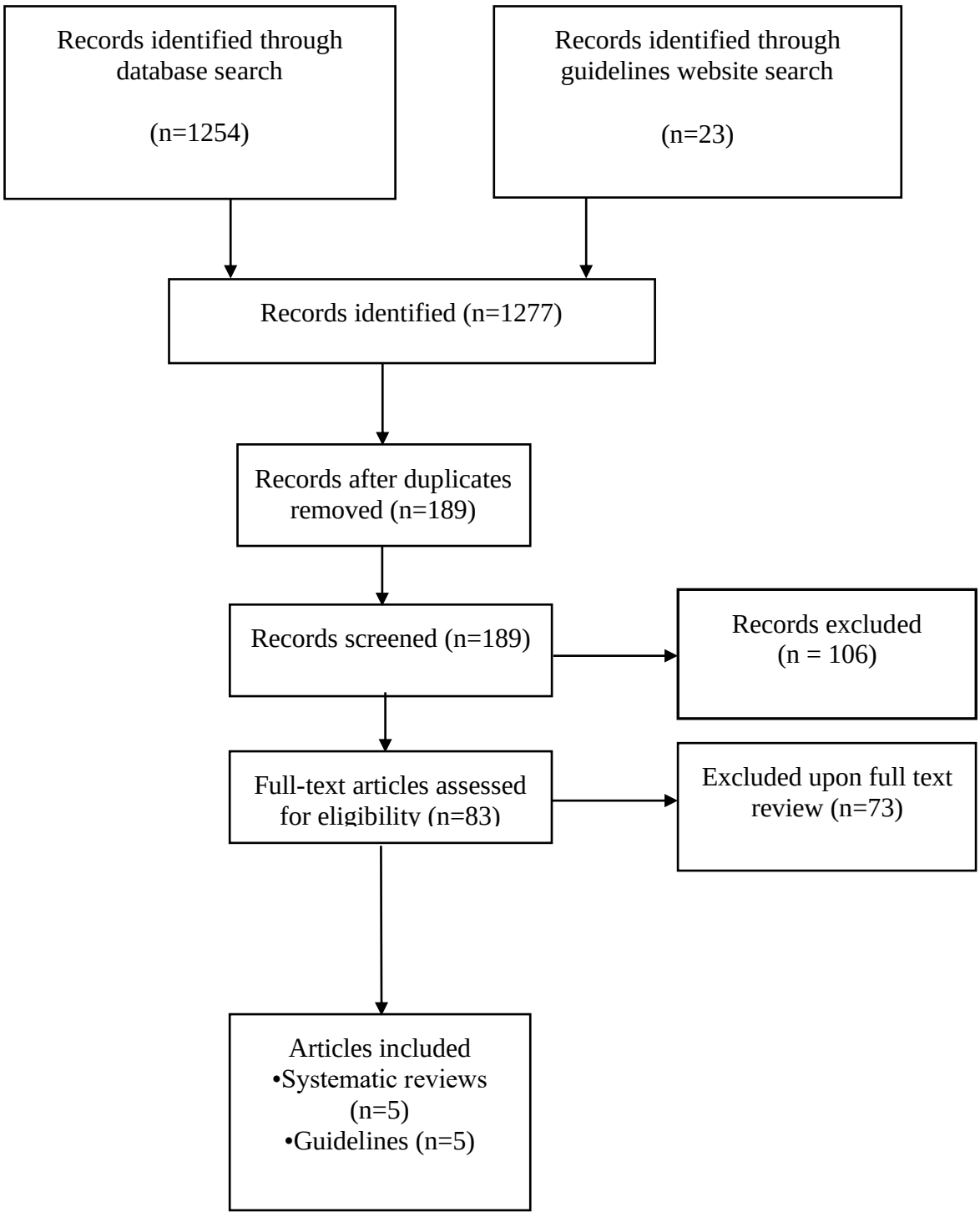


Figure 4: PRISMA flow chart

6.6 The identified barriers

Barriers to oral healthcare identified in this thesis included parents' lack of awareness of oral health issues, behavioural issues faced by the parents when supporting at-home oral health care, behavioural issues faced by members of the dental team when treating patients in clinic, and lack of access to care due to limited availability of specialised oral healthcare facilities and providers.

The understanding of the barriers and limitations to appropriate oral healthcare for children with SHCNs , as perceived by the parents, is important for improving the oral health children condition and effectively promoting it in future interventions (361,364).

For the purpose of this chapter, we focused on three key barriers:

- Access to dental services
- Behaviour management
    - At home
    - In clinic
- Preventive measures
    - At home
    - In clinic

6.7 Access to appropriate dental care

Finding a dentist that can accommodate the oral health needs for children with SHCNs was reported to be difficult by the parents in our qualitative study. It must be noted that the limited access to dental care might reflect either the lack of dentists with expertise or the unwillingness of the dental team to treat children with SHCNs (283). In addition, parents or caregivers of children with SHCNs may be discouraged from seeking oral care because of the attitude of oral care providers toward their children or themselves. It is often a demanding situation for parents and caregivers of children with SHCNs to find a dental clinic that accepts their children or are

able to accommodate their needs. This can cause frustration among the caregivers especially if the child has behavioural issues or are unable to cooperate.

One of the perceived barriers highlighted in this thesis was the inability of oral care providers to manage children with SHCNs. The lack of a suitable provider to manage oral care for children with SHCNs has been documented in several studies (61,361). Many studies have reported a lack of sufficient professional preparation in meeting the needs of these children, which is considered one of the main reasons why, according to caregivers, oral care providers failed to treat children with SHCNs (46,361,367). Looking particularly at the limited access to specialised oral care services, several authors have found that some oral care providers find the delivery of oral care for children with SHCNs excessively stressful and challenging (107). In addition, certain oral care providers, be it because of perceived inadequate compensation or time constraints, are not motivated to see or provide treatment to these children (14). The lack of training among dental practitioners while they are in dental school indicates that professionals are not fully prepared to meet such a demand because of their insufficient theoretical knowledge (107).

6.7.1 Search results

Two systematic reviews (379,380) and two clinical guidelines (162,381) were identified relating to access to dental care for children with SHCNs. The characteristics of these publications are presented in Tables 13 to 16, along with individual GRADE assessments.

RCS England (2012) Clinical guidelines and integrated care pathways for the oral health care of people with learning disabilities (162) http://www.wales.nhs.uk/documents/BSDH_Clinical_Guidelines_PwaLD_2012.pdf Aim: to provide local guidelines and protocols to improve the oral health of people with learning disabilities.				
Population and setting	**Intervention/Exposure**	**Intervention/Exposure provider**	**Comparison**	**Outcomes**
Population: People with learning disabilities **Setting**: A range of settings including: Community, hospital, primary care dentistry, residential, schools	• Increase awareness of oral care – Information on accessible services – Early referral to the dentist – Alternative ways of delivering oral healthcare (e.g., home visits, mobile dental units) – Increase dental attendance (Acclimatisation) – Access to general anaesthesia if needed, treatment under sedation and general anaesthesia should be made available. – The need for a regular oral assessment and based on individual's needs – Carers should be encouraged to obtain an oral health assessment for their children • Oral Health Screening/working with – Education programmes, oral hygiene, personal hygiene training and promotion of healthy policies)	Health care provider /multidisciplinary care/caregivers/ school staff and teachers	No intervention or other active intervention	Access to care/ oral health
Included studies	**Additional criteria**			

10 guidelines,10 Policy documents, 1 systematic review and 1 RCT	A systematic review was carried out in producing this guideline. Recommendations were listed without referencing the individual body of evidence. (recommendation were labelled using SIGN grading level but not linked to the individual body of evidence).

Overall results/recommendations	**GRADE evidence certainty rating**
Recommendations regarding how to improve access to dental services Primary Care Trusts, Health Boards or equivalent responsible bodies have a duty of care for their local population • Ask local responsible bodies if they have carried out a need's assessment. If yes, what were the findings and what are they doing as a result of the findings? If no, when are they planning to do the assessment? • Commissioners should encourage Health Improvement Programmes • Joint Investment Plans should ensure collaboration between Health Authorities and Social Services/Social Work Departments • Commissioners should encourage Joint Investment Plans that ensure oral health is integral to the development of services • Promote oral health care by working with various agencies • Be involved in the development of joint policies • Encourage development of personal skills to promote health • Facilitate programmes in prevention for health gain • Social Services/Social Work Departments should lead the way in care and support • Encourage Health Care Professionals to provide support and help meet health care needs • Enable Community Learning Disability Teams to help with access to dental care • Encourage Community Learning Disability Teams to include representatives from the dental profession **Training and education** *For dental students* • Ethics and jurisprudence (General Dental Council, 1999) relating to understanding the position of people with learning disabilities should be taught as components of the course to further the understanding of the student • The teaching of verbal and non-verbal communication techniques should be included as part of the course • Emphasis should be placed on valuing the individual and the avoidance of stereotyping, which is accomplished through the inclusion of disability awareness, behavioural sciences and special care dentistry	**Not undertaken**

Postgraduate Education • Formal postgraduate courses leading to a recognised qualification should be actively promoted • Postgraduate Deans and commissioners of postgraduate education should be encouraged to fund courses in conjunction with the Salaried Primary Care Dental Services • The care of people with learning disabilities should be an essential component of Dental foundation training for dentists. Experience in General Dental Practice, the Salaried Dental Services and Hospital • Service posts should be arranged to consolidate their professional development *Training for dental care professionals* • Integrated study days should be developed with other health care professionals • Courses need to be available nationwide • Courses should be developed which will enable DCPs to provide training to groups of health professionals and carers • Collaborative study days should be available locally and nationally, where information can be exchanged with colleagues from other disciplines *Training for carers and other health care professionals* • Oral health should be included within the undergraduate curriculum for medical students • Formal and informal training in oral care should be provided for all carers and healthcare professionals such as dieticians, occupational therapists etc • Oral health should be a core subject in the curriculum for general nursing degrees and diplomas	
GRADE rating explanation	
Unable to undertake GRADE assessment due to lack of information on the underpinning evidence. However, the recommendations are graded as C within the document, being based on expert committee reports or opinions and/or clinical experience of respected authorities. The applicability to KSA for some of the recommendations regarding access to services is questionable due to the variations in the structure of dental services. Recommendations regarding training and education are more applicable.	
OVERALL SUMMARY	

The document provides recommendations aimed at informing healthcare providers, multidisciplinary caregivers and school staff about how to improve the oral health of people with learning disabilities. Whilst the publication provides clear recommendations on prevention and treatment, there is a lack of high certainty evidence to support methods for improving access or training/education.

Table 13: Clinical guidelines and integrated care pathways for the oral health care of people with learning disabilities

SDCEP (2018) Prevention and Management of Dental Caries in Children (381)
https://www.sdcep.org.uk/wp-content/uploads/2018/05/SDCEP-Prevention-and-Management-of-Dental-Caries-in-Children-2nd-Edition.pdf
Aim: to provide recommendations for improving oral health in children

Population and setting	**Intervention/Exposure**	**Intervention/Exposure provider**	**Comparison**	**Outcomes**
Population: Children **Setting**: A range of settings including: community, hospital, primary care dentistry, residential, schools	• Assess to oral care unit under sedation or general anaesthesia for children with disability • Consider referral for to assess care for extractions under sedation or general anaesthesia for disabled children	Health care professionals Family/parent	N/A	Access to care/ oral health

Included studies	**Additional criteria**
N/A	Evidence base for children with SHCNs in this guidance is limited and based on British Society of Paediatric Dentistry Non-pharmacological behaviour management guideline (the underpinning evidence excluded children with disability).

Overall results/recommendations	**GRADE evidence certainty rating**
Service provision/referrals • Only refer cases after appropriate local treatments have been exhausted • Be aware of the referral options available locally and the agreed referral procedures. • When referring, ensure that this is to the appropriate service and that the agreed local procedures are followed. • For children who live in a different locality than your practice, beware that you should refer to the service local to the child. This may be different to the service you routinely refer too.	**Not undertaken**

• If a child is referred for care, ensure that you provide their continued dental care. • Increasingly, electronic referral systems are being implemented. However, in situations where you are writing a referral letter ensure all the relevant information is included • After a child has received care with sedation or GA, ensure that ongoing preventive care is provided. **Recall** • Assign a recall interval that is based on caries risk and specific to the oral health needs of the child. • Carry out a focused oral health review, including asking again about toothbrushing practice and dietary habits. • Enquire about compliance with agreed action plans. • Closely monitor lesions managed with prevention alone. Consider recording plaque scores on the surface of the lesions, recording caries progression via radiographs or photography and ensure the parent/carer is made fully aware of their responsibility. If caries progresses, consider another option. • Check the condition of fissure sealants: visually for wear and physically for integrity or leakage • Reassess the child's caries control and caries risk • If caries is not being effectively controlled by the parent/carer or the child, consider the possibility of dental neglect and the need for additional support • If the child is assessed as at increased risk of developing caries, provide Enhanced Prevention at 3 monthly intervals. Otherwise, provide Standard Prevention at 6 monthly intervals, or exceptionally at longer intervals (e.g. for an older child if justified and recorded) • Ensure comprehensive records are maintained and create a new personal care plan as required.	
GRADE rating explanation	
GRADE assessment not undertaken as recommendations not linked to specific evidence, although Guideline development process well documented and follows clear methodology. The applicability of the evidence to children with SHCN should be considered	
OVERALL SUMMARY	

The guidelines provide best practice points regarding referral and recall, however, no clear recommendations on improving access are identified

Table 14: Prevention and management of dental caries in children

Rosa et al. (2020) Barriers in Access to Dental Services Hindering the Treatment of People with Disabilities: A Systematic Review (379)
https://www.hindawi.com/journals/ijd/2020/9074618/
Aim: to provide a critical overview of the literature concerning barriers and facilitators of access to oral health services for people with disabilities

Population and setting	**Intervention/Exposure**	**Intervention/Exposure provider**	**Comparison**	**Outcomes**
Population: People with Disabilities **Setting**: Community setting. Hospital setting Dental setting Residential setting	• Physical or nonphysical barriers to access dental services: – dentist's lack of preparation, structural problems, financial barriers and communication difficulties, – lack of awareness regarding dental treatment	Dental care professionals/Enforce government policy/parent	N/A	Increase access to care
Included studies	**Additional criteria**			
16 studies observational studies (cross-sectional, cohort, and case-control)	Quality of the articles was assessed by two independent reviewers using the Downs and Black scale.			
Overall results/recommendations				**GRADE evidence certainty rating**
No pooling of data undertaken due to wide variation between studies. Only one study showed a low risk of bias for all the assessed items. Only 4 studies were relevant to our target group (children with SHCNs).				**Very low[1]**

Although several barriers were identified, none of the selected studies discussed facilitators of access to oral health services for people with disabilities.	
GRADE rating explanation	
1. Evidence based on observational studies at high risk of bias	
OVERALL SUMMARY	
The systematic reviews highlight the need for research around how best to facilitate access to dental care services in the target population. In addition, authors conclude "There is a need to improve the training rendered to dentists pertaining to care for this population in various national and regional contexts. It would be ideal to enforce and implement accessibility laws in every country."	

Table 15: Barriers in access to dental services hindering the treatment of people with disabilities: a systematic review

Kuhlthau et al. (2011) Evidence for family-centered care for children with special health care needs: a systematic review (380)
https://pubmed.ncbi.nlm.nih.gov/21396616/
Aim: to evaluate family-centred care for children with special health on health care ("families of children with special health care needs will partner in decision making at all levels and will be satisfied with the services they receive").

Population and setting	**Intervention/Exposure**	**Intervention/Exposure provider**	**Comparison**	**Outcomes**
Population: Children with special health care needs **Setting**: Community setting. Hospital setting Residential setting	Intervention to promote family-centred care (FCC) associations between FCC and access care.	Family members and health or service care providers	N/A	Access to care/System improvement
Included studies	**Additional criteria**			
Twenty-four studies Eight were cross-sectional studies, 7 were randomized controlled trials				
Overall results/recommendations				**GRADE evidence certainty rating**
The authors reported a positive association of FCC with improvements in the use of health services, and access to care. The authors included studies that were above a score of 12 using the metric of Downs and Black (only done by one author). The included studies varied greatly in intervention and the outcomes measures. No discussion around bias in the included studies. No pooling of data undertaken due to the heterogeneity variation between studies.				**Very low[1]**

GRADE rating explanation
1- Downgraded due to study design and indirectness
OVERALL SUMMARY
Limited evidence to support the effectiveness of family-centred care for children with special health to improved access for children with SHCNs. This was due to an inconsistency and indirectness of the evidence.

Table 16: Evidence for family-centered care for children with special health care needs: a systematic review

6.7.2 Summary of evidence

Two guidelines were identified and included in this evaluation (162,381) (Tables 13-14). The quality of the underpinning evidence was discussed in the included guidelines; however, a GRADE assessment was not undertaken for the guidelines as the recommendations were not linked to specific evidence. Otherwise, the guidelines development process was well documented and followed clear methodology. The recommendation listed within the two guideline documents provide recommendations aimed at increase awareness of oral care services, training and education for both oral care provider and parent, and provision oral care services such as arranging appointment and referral process.

A further two systematic review were identified (379,380) (Tables 15-16). The evidence included in both reviews varied, despite both reviews assessing related access issues. One review included randomised controlled trials (RCTs) and observational studies while the other review included only observational studies. The quality of the studies included in both reviews was assessed by using the Downs and Black scale. One review also assessed the risk of bias of the included studies using Cochrane risk of bias tool (379). The total number of studies included in each review varied from 16 to 24. Although several barriers were identified in the review, one of the selected studies discussed facilitators of access to health services for children with SHCNs (380). Limited evidence reported that family-centred care for children with SHCNs may improve the use of health services, and access to care (380). The certainty of the evidence is very low due to an inconsistency and indirectness of the evidence.

There is limited evidence to inform or implement facilitator interventions to increase access to dental care for children with SHCNs. However, we identified two broad types of intervention from the included guidelines that seems to suggest there is a potential benefit of: increased awareness of care and educational and training programmes for both carers and oral health care professionals. Increasing the awareness and knowledge of caregivers or parents of these children about the availability of various facilities for dental treatment may potentially eliminate some of the access related concerns.

Providing easily accessible information about nearby dental clinics, such as an online dental directory comprising the names of all the dental clinics that effectively treat children with SHCNs, may minimise delays in obtaining oral care.

Training programmes to address issues around access should include courses focussing on the continuing professional development of dental care staff; programmes to provide key information about behavioural, mental and physical challenges in caring for children with SHCNs; and providing information on effective ways of providing dental care to children with SHCNs in the dental setting. These programmes can be provided by means of face-to-face workshops or online modules and should be made mandatory for all oral care providers. It is equally important to investigate whether the dental system in Saudi Arabia has sufficient qualified dentists and sufficient resources for appropriate dental treatment for children with SHCNs to enable the promotion of oral care.

Although, oral health educational and training program may be useful approach to deliver for children with SHCNs, the benefit of these approaches is limited since it was based on guidelines that were developed for a different community with a different dental setting. As a result. the evidence's applicability to children with SHCNs in SA is still unknown.

6.7.3 Implications for practice and research

There is insufficient evidence to draw firm conclusions as to how best to increase access to oral care services for children with SHCNs. This review has emphasized a significant gap in the current literature for facilitator intervention to increase access for oral care for children with SHCNs. As result a reliable conclusion cannot be drawn. There is need for greater discussion around this issue and the production of high-quality evidence to underpin future recommendations for delivering care to this population.

Key implications:

- A needs assessment should be undertaken to determine if sufficient resources/workforce are in place to provide appropriate levels of care
- Improved dental training of undergraduate and postgraduate students to meet the oral need of children with SHCNs
- Improved CPD around providing oral health care for children with SHCNs

- Providing accessible information about the existing oral care services for both carers and children with SHCNs
- Well-designed primary studies and robust clinical guideline are urgently required in order to inform relevant stakeholders.

6.8 Behaviour management

Behavioural issues of children with SHCNs were among the main perceived concerns reported by parents both at home and when receiving oral care in clinic. Temper tantrums and emotional outbursts are some forms of anxiety displayed when children with SHCNs become anxious and non-compliant during home care. These behaviours can be a result of the frustrations of the child because of the disruption of their daily routine or them becoming anxious in an unfamiliar setting, like that of a dental care unit. Their potentially aggressive behaviours – in more serious cases – often translate into kicking, biting, scratching and even destruction of fixtures around them. The severity of such behaviours can be a result of deficit in the type of need and shortfall in language development (202). The child themselves can also present barriers to his or her treatment, due to a possibility of fear of dentists or a lack of cooperation.

A number of studies have indicated a high level of anxiety and fear in children with SHCNs (162,353). Evidence show that fear is related to the frequency of dental visit and as result could impact the status of oral health especially for children with SHCNs (128). This might set a negative stage and perception of a dental clinic among these children. Negative reactions may often be seen or observed in the waiting rooms, ultimately resulting in appointment cancellation before it has even begun. Challenging behaviours, in dental setting, can be defined as self-injurious behaviours, sensory hypersensitivity, hyperactivity and non-compliance actions (89). Some children with SHCNs are hypersensitive to stimuli such as auditory or tactile, making the environment of dental care units very stressful, thereby triggering conditioned fear such as autistic children (162). Moreover, for some children it might be difficult for them to sit still in the chair, and they may need restraint and protective stabilization (382). If children with SHCNs showcase severe disruptive behaviour a treatment under GA may be required to deliver adequate oral care.

Behavioural challenges, in addition to complex medical as well as physical conditions, can make it difficult for the oral care providers without the requisite knowledge and expertise to provide the required treatment. As result some practitioners may avoid providing treatment to individual with SHCNs or react with apathy and frustration as it requires more efforts and time (383).

The challenges in providing adequate oral care to children with SHCNs have been acknowledged in many studies (384). Challenges in the management of children with SHCNs can be a result of poor tolerance, behavioural issues and lack of cooperation, inexperience of the oral care provider and lack of effective support from caregivers during care. It is important to educate caregivers, practitioners and other relevant agencies on the management of dental health care needs, especially those of children with special healthcare needs. Children with SHCNs are a heterogenous group that have different levels of needs. Some of them may have the ability to comply with oral care with basic behavioural techniques especially when the oral care provider has the willingness, expertise and knowledge to deliver the required care; others may not (385).

The barriers from the perspective of parents of children with SHCNs have been divided into two categories by Nelson et al., which include the nonenvironmental and the environmental category. Some of the environmental barriers, as defined by Nelson et al., included the difficulty in finding a dental clinic with staff members willing and trained to manage and accept children with SHCNs. The nonenvironmental barriers included the child's fear of treatment, their uncooperative behaviour during treatment, other urgent healthcare needs and their perceived fear of a dental clinic environment or a dentist (50).

6.8.1 Search results

One systematic review and three guidelines were identified relating to behaviour management of children with SHCNs. The characteristics of these publications are presented in Tables 17 to 20, along with individual GRADE assessments.

RCS England (2012) Clinical guidelines and integrated care pathways for the oral health care of people with learning disabilities (162)
http://www.wales.nhs.uk/documents/BSDH_Clinical_Guidelines_PwaLD_2012.pdf
Aim: to provide local guidelines and protocols to improve the oral health of people with learning disabilities. The focus on both professional and multidisciplinary care.

Population and setting	**Intervention/Exposure**	**Intervention/Exposure provider**	**Comparison**	**Outcomes**
Population: people with Learning Disabilities **Setting**: A range of settings including: Community, hospital, primary care dentistry, residential, schools	• Communicating with People who have Learning Disabilities • Behaviour management of people with learning disability through Use of General anaesthesia and Sedation	Health care professionals Caregivers School staff and teachers	N/A	Behaviour management

Included studies	**Additional criteria**
The guideline referenced 10 guidelines,10 Policy documents,1 systematic review and one RCT.	A systematic review was carried out in producing this guideline. Recommendations were listed without referencing the individual body of evidence. (recommendation were labelled using SIGN grading level but not linked to the individual body of evidence).

Overall results/recommendations	**GRADE evidence certainty rating**
Recommendations regarding how to improve communication and behaviour management of people with learning disability • Communicating (graded C according to SIGN):	**Not undertaken**

– Oral healthcare provider should know and record the preferred method of communicating with the child. – Appropriate language must be used (Speech slow and clear). – The Oral Health Care Team should be trained with communication skills. – Treatment should be started with nonpharmacological and non-surgical methods. • Behaviours management (graded C according to SIGN) – Use of Sedation for children with learning disability – Each person should be assessed individually – Appropriate facilities and equipment should be available/training staff – Distraction and behavioural psychology is a useful management option. – Each person should be assessed individually – Appropriate facilities and equipment should be available – The whole dental team should have appropriate training and updates • Use of General – The appropriate resources and facilities for general anaesthetics should be available. – General anaesthesia should be the last choice for treatment. – Collaborative work should be done to minimise the number of general anaesthetics required.	
GRADE rating explanation	
Unable to undertake GRADE assessment due to lack of information on the underpinning evidence. However, the recommendations are graded as C within the document, being based on expert committee reports or opinions and/or clinical experience of respected authorities.	
OVERALL SUMMARY	
The document provides recommendations aimed at informing healthcare providers about alternative behaviour management at the dental office. There is no discussion about management of children behaviour at home.	

Table 17: Clinical guidelines and integrated care pathways for the oral health care of people with learning disabilities

SDCEP (2018) Prevention and Management of Dental Caries in Children. (381)
https://www.sdcep.org.uk/wp-content/uploads/2018/05/SDCEP-Prevention-and-Management-of-Dental-Caries-in-Children-2nd-Edition.pdf
Aim: to provide recommendations for improving oral health in children

Population and setting	**Intervention/Exposure**	**Intervention/Exposure provider**	**Comparison**	**Outcomes**
Population: Children **Setting**: A range of settings including: Community, hospital, primary care dentistry, residential, schools	• Therapeutic procedure of behaviour Management in dental clinic	Health care professionals Family/parent	N/A	Behaviour management

Included studies	**Additional criteria**
N/A	Evidence base for children with SHCNs in this guidance is limited and based on British Society of Paediatric Dentistry Non-pharmacological behaviour management guideline (the underpinning evidence excluded children with disability).

Overall results/recommendations	**GRADE evidence certainty rating**
Consider the use of one or a combination of the following behaviour management strategies to facilitate provision of both preventive care and treatment: • Communication; Enhancing control; Tell, show, do; Behaviour shaping and positive reinforcement; Structured time; Distraction; Relaxation; Systematic desensitisation. **Referral for GA/Sedation** Before referring a child for treatment with sedation or GA, first relieve pain, provide prevention and attempt caries treatment using behavioural management techniques and local anaesthesia if indicated.	**Not undertaken**

If referring a child for sedation or GA, follow your local protocol if there is one in place. Consider the need for temporary dressings to reduce the chance of further pain. Advise the parent/carer and child that their first visit to the centre will probably be for assessment only. Include all relevant information in the referral letter, such as radiographs if available, and state why in your opinion, sedation or GA is required Do not promise the child and parent/carer that either sedation or GA will be provided; this decision must be made by the clinician at the referral centre. For further information consult the *Guideline for the Use of General Anaesthesia (GA) in Paediatric Dentistry*.	
GRADE rating explanation	
GRADE assessment not undertaken as recommendations not linked to specific evidence, although Guideline development process well documented and follows clear methodology. The applicability of the recommendations to children with SHCNs is unclear	
OVERALL SUMMARY	
The guidelines provide a range of best practice points regarding behaviour management technique in dental clinic; no clear recommendations on behaviour management at home or specifically linked to the management of children with SHCNs	

Table 18: Prevention and management of dental caries in children. (Scottish Dental Clinical Effectiveness Programme)

AAPD (2020) Management of Dental Patients with Special Health Care Needs (91)
https://www.aapd.org/media/Policies_Guidelines/BP_SHCN.pdf
Aim: to provide recommendations for the management of patients with SHCNs

Population and setting	**Intervention/Exposure**	**Intervention/Exposure provider**	**Comparison**	**Outcomes**
Population: Patients with SHCNs **Setting**: A range of settings including: dental setting	• Therapeutic procedures for the of management of patients during dental care – Patient communication – behaviour guidance	Oral health care providers/staff/parent	N/A	Behaviour Management High-quality patient care

Included studies	**Additional criteria**
	No quality assessment for the included studies with no information about the underpinning evidence.

Overall results/recommendations	**GRADE evidence certainty rating**
Patient communication When treating patients with SHCN communication is critical. -Information provided by a parent or caregiver prior to the patient's visit can assist greatly in preparation for the appointment. -An attempt should be made to communicate directly with the patient and, when indicated, to supplement communication with gestures and augmentee methods of communication during the provision of dental care. -A patient who does not communicate verbally may communicate in a variety of non-traditional ways. -At times, a parent, family member, or caretaker may need to be present to facilitate communication and/or provide information that the patient cannot.	**Not undertaken**

-Dentist must work with those individuals to establish an effective means of communications. **Informed consent** All patients must be able to provide signed informed consent for dental treatment or have someone present who legally can provide this service for them. Informed consent/assent must comply with state laws and, when applicable, institutional requirements. Informed consent should be well documented in the dental record through a signed and witnessed form. **Behaviour guidance** Behaviour guidance of the patient with SHCN can be challenging (Because of dental anxiety or a lack of understanding of dental care) children with disabilities may exhibit resistant behaviours. -These behaviours can interfere with the safe delivery of dental treatment. -With the parent/caregiver's assistance, most patients with physical and mental disabilities can be managed in the dental office. **-Protective stabilization** can be helpful in patients for whom traditional behaviour guidance techniques are not adequate. When protective stabilization is not feasible or effective, **sedation or general anaesthesia is the behavioural guidance armamentarium** of choice. -When in-office sedation/ general anaesthesia is not feasible or effective, an out-patient surgical care facility might be necessary.	
GRADE rating explanation	
GRADE assessment not undertaken as recommendations not linked to specific evidence.	
OVERALL SUMMARY	
The document provides a professional approach that can be delivered during care; no clear recommendations on behaviour management at home	

Table 19: Management of dental patients with special health care needs

Monteiro et al. (2020) Interventions for increasing acceptance of local anaesthetic in children and adolescents having dental treatment (386)
https://www.cochranelibrary.com/cdsr/doi/10.1002/14651858.CD011024.pub2/full
Aim: To evaluate the effects of different methods for acceptance of LA in children and adolescents with and without SHCNs during dental treatment.

Population and setting	**Intervention/Exposure**	**Intervention/Exposure provider**	**Comparison**	**Outcomes**
Population: Children and adolescents with and without SHCNs **Setting**: A range of settings including; dental setting	• Audio-visual distraction compared to conventional treatment. • The wand versus conventional treatment • Counter-stimulation/distraction versus conventional treatment • Hypnosis versus conventional treatment	Health care professionals	No intervention or other active intervention	Acceptance of LA Completion of dental treatment Successful LA/painless treatment Patient satisfaction:

Included studies	**Additional criteria**
26 RCTs	

Overall results/recommendations	**GRADE evidence certainty rating**
Audiovisual distraction compared to conventional treatment: The evidence was uncertain for the outcome pain-related behaviour during delivery of LA with a reduction in negative behaviour when 3D video glasses where used in the audiovisual distraction group (risk ratio (RR) 0.13, 95% confidence interval (CI) 0.03 to 0.50; 1 trial, 60 participants; very low-certainty evidence).	**Ver Low[1]**

The wand versus conventional treatment: The evidence was uncertain regarding the effect of the wand on pain-related behaviour during delivery of LA. Four studies reported a benefit in using the wand while the remaining studies results suggested no difference between the two methods of delivering LA (six trials, 704 participants; very low-certainty evidence). **Counter-stimulation/distraction versus conventional treatment** The evidence was uncertain for the outcome pain experience during delivery of LA with children experiencing less pain when counter-stimulation was used (RR 0.12, 95% CI 0.04 to 0.34; 1 trial, 134 participants; very low-certainty evidence). **Hypnosis versus conventional treatment:** The evidence was uncertain for the outcome pain experience during delivery of LA with participants in the hypnosis group experiencing less pain (mean diffrence (MD) -1.79, 95% CI -3.01 to -0.57; 1 trial, 29 participants; very low-certainty evidence). The authors did not find any evidence about increase acceptance of LA in children and adolescents with special healthcare needs were	**Ver Low[2]** **Ver Low[3]** **Ver Low[3]**
GRADE rating explanation	
1- Downgraded for high risk of bias, imprecision and indirectness. 2- Downgraded for high risk of bias, imprecision and indirectness. 3- Downgraded for high risk of bias, imprecision and indirectness.	
OVERALL SUMMARY	
The authors reported that no reliable evidence about acceptance of LA in children and adolescents with special healthcare needs were found. This area of evidence is limited, and further research is needed.	

Table 20: Interventions for increasing acceptance of local anaesthetic in children and adolescents having dental treatment

6.8.2 Summary of evidence

A total of three guidelines were identified and included in this evaluation (91,162,381) (Tables 17-19). The quality of the underpinning evidence was only discussed in two guidelines (20,21). The recommendation listed within the guidelines are aimed at informing healthcare providers, and dental staff about different behavioural and communication strategies to increase children's compliance while delivering care. The GRADE assessment was not undertaken for all guidelines as recommendations were not always linked to specific evidence.

Enhancing communication and behaviour guidance, such as the use of protective stabilization, sedation or general anaesthesia during dental treatment were the general themes of the included guidelines. There is limited evidence to inform or implement behavioural interventions from the existing guidelines for children with SHCNs with regard to management techniques that can be used at home. Current guidelines seem to focus on potential clinical framework or behavioural management approaches such as GA and sedation, specifically directed toward clinician.

One systematic review was identified within literature and included in this evaluation (386). The review included 24 RCTs and evaluated different methods to increase acceptance of LA during dental treatment. The authors reported that there is no reliable evidence within the literature for children and adolescent with SHCNs and further research is needed (Tables 20).

The aim of this section is to identify potential evidence-based interventions that would be appropriate to address behavioural issues for children with SHCNs both at home and at dental office. Whilst guidelines discuss behaviour or management approaches, there was a lack of evidence to support many of these approaches. Furthermore, none of the studies were conducted in Saudi Arabia and as result the applicability of professional behaviour management approaches discussed in the guidelines is unknown.

6.8.3 Implications for practice and research

We did not find sufficient evidence to draw a firm conclusion with regard to the behavioural management of children with SHCNs. A difficulty in the development of a sound evidence base in this area is the wide variation in individual behaviours/needs. Whilst there is a need for high-quality evidence to address the issue of behavioural management both at home and at dental office, this variation in children's needs should be considered.

Despite behavioural issues being highlighted as one of the main concerns reported by parents in Chapter Five, the evidence to support parents in this regard is limited. Caregivers and children with SHCNs need to be supported and motivated to increase their confidence when carrying out oral hygiene routines despite children's behavioural issues. The role of oral care professional goes beyond providing oral care treatment for children with SHCNs in the dental setting. The ability of the dental team to help parents and children to develop practical approaches to oral hygiene at home is of utmost importance. This requires proper knowledge and experience with these children and sympathy for the issues that parents have to deal with when providing home care. A discussion around the difficulties in home oral care practices between caregivers and oral care providers may uncover issues that can be resolved and would have otherwise gone unaddressed. It is important for the clinicians to work closely with parents of children with SHCNs to seek their input and come up with a customised home oral hygiene plan in order to improve their overall oral condition.

Key implications:

- Clinicians should engage in discussions with caregivers and help develop achievable, customised home oral hygiene plan in order to improve their overall oral condition
- An exploration of behavioural management techniques from outside the dental profession may help inform oral care both within the dental setting and at home
- Well-designed primary studies and robust clinical guideline are urgently required in order to inform relevant stakeholders.

6.9 Preventive measures

Effective strategies and tasks for maintaining oral hygiene are more important for children with SHCNs as they may lack cognitive skills and manual dexterity to understand or perform efficient oral hygiene (292). Other related conditions may also be present in these children, such as behavioural conditions, chronic medical conditions, anxiety or sensory impairment that might negatively impact their oral hygiene routine. In one study, parents of children with SHCNs identified some key issues resulting from the disability of their children such as a tendency to gag, an oversensitive mouth, difficulty using a toothbrush, and an inability to rinse the mouth (387). Moreover, parents of these children are usually not trained properly and also lack proper knowledge of the importance of oral hygiene and therefore do not see oral hygiene as a priority (369). To overcome these barriers, children with SHCNs require encouragement and support with their oral hygiene from both oral care provider and caregivers (388).

6.9.1 Search results

Two systematic reviews (389,390) and three guidelines (162,169,391) were identified relating to preventive measures for children with SHCNs. The characteristics of these publications are presented in Tables 21 to 25, along with individual GRADE assessments.

RCS England (2012) Clinical guidelines and integrated care pathways for the oral health care of people with learning disabilities (162)
http://www.wales.nhs.uk/documents/BSDH_Clinical_Guidelines_PwaLD_2012.pdf
Aim: provide local guidelines and protocols to improve the oral health of people with learning disabilities.

Population and setting	**Intervention/Exposure**	**Intervention/Exposure provider**	**Comparison**	**Outcomes**
Population: People with learning disabilities **Setting**: A range of settings including: Community, hospital, primary care dentistry, residential, schools	Prevention intervention • Dietary advice • Use of Fluoride • Fissure Sealants • Oral Health Education, Oral Health Screening, Education and Training of Parents, Carers	Health care professionals Multidisciplinary care Caregivers/parent School staff /teachers	N/A	Prevention and Promotion of Oral Health

Included studies	**Additional criteria**
10 guidelines, 10 Policy documents, 1 systematic review and one RCT	Systematic review was carried out in producing this guideline. Recommendations were listed without referencing the individual body of evidence. (recommendation were labelled using SIGN grading level but not linked to the individual body of evidence).

Overall results/recommendations	**GRADE evidence certainty rating**
• Dietary advice (graded B according to SIGN): – Limit sugary foods and drinks/Cariogenic snacks/ /Sugars should not be added to bottles – Preventative advice should be offered • Use of Fluoride (graded A according to SIGN): – Brushing to start when the first tooth erupts	**Not undertaken**

– Children under the age of 3 years should only use a smear of toothpaste 1000ppm – Children aged 3-6 years with an impairment or disability, should use a pea sized amount of 1350ppm – Children aged 7 plus years should be encouraged to use 1350-1500ppm fluoride – Children at higher risk above the age 10 years and can use toothpaste containing 2800ppm fluoride – Direct supervision by an adult is advisable – Parents should be fully involved – Topical fluoride should be applied biannual • Fissure Sealants (graded C according to SIGN): – Children at risk of dental caries should have fissure sealants applied to permanent teeth – Parents should be advised of the need for the need and maintenance of fissure sealants • Oral Health Education, Oral Health Screening, Education and Training of Parents, Carers and Professionals Initial Visit, Regular Attendance, Oral Health Screening program include (graded C according to SIGN): – Screening programmes /Local programmes To establish: – Oral health education programmes – Educational Plan – Oral training – Healthy eating policies – The needed support for both the parent and the child	
GRADE rating explanation	
Unable to undertake GRADE assessment due to lack of information on the underpinning evidence. However, the recommendations are graded as A-C within the document, varying from high quality evidence to expert committee reports or opinions and/or clinical experience of respected authorities.	

OVERALL SUMMARY
The document provides recommendations aimed at informing healthcare providers, multidisciplinary caregivers and school staff about how to improve the oral health of people with learning disabilities.

Table 21: Clinical guidelines and integrated care pathways for the oral health care of people with learning disabilities

PHE (2017) Delivering better oral health: an evidence-based toolkit for prevention (391)
https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/605266/Delivering_better_oral_health.pdf
Aim: to provide recommendations for the prevention of poor oral health

Population and setting	**Intervention/Exposure**	**Intervention/Exposure provider**	**Comparison**	**Outcomes**
Population: General population **Setting**: A range of settings including: Community, hospital, primary care dentistry, residential, schools	• Prevention of caries in children with special need both at home and at dental office	Health care professionals/ policy makers/ patients	N/A	Caries management

Included studies	**Additional criteria**
Several high-quality systematic reviews were included to support the recommendation	The grades of evidence in the guideline are based on Gray (1997)

Overall results/recommendations	**GRADE evidence certainty rating**
• Prevention of caries in children with special need (age 0-6yrs) at home – Sugar should be limited – Parents/carers should brush or supervise toothbrushing (EB: I) – As soon as teeth erupt brush should start twice daily with a fluoridated toothpaste (EB: I) – Brush last thing at night (EB: III) – Use fluoridated toothpaste containing no less than 1,000 ppm fluoride (EB: I)	**Not undertaken**

– Use fluoridated toothpaste containing 1,350-1,500 ppm Fluoride (EB: I) – Use only a smear or pea size amount of fluoride – Request medication that is sugar free for long term (EB: III) • Prevention of caries in children with special need (age 0-6yrs) at the dental office (age 0-6yrs) – Apply fluoride varnish to teeth two or more times a year (2.2% NaF-) (EB: I) – Reduce recall interval – Investigate diet and assist adoption of good dietary practice in line with the Eatwell Guide (EB: I) • Prevention of caries in children with special needs aged from 7 years and young adults at home All the above plus – Use a fluoride mouth rinse daily (0.05% NaF) at a different time to brushing (EB: I) • Prevention of caries in children with special needs aged from 7 years and young adults at the dental office – Fissure seal permanent molars with resin sealant (EB: I) – Apply fluoride varnish to teeth two or more times a year (2.2% NaF-) (EB: I) – For those 8 years upwards with active caries prescribe daily – fluoride rinse (EB: I) – For those 10+ years with active caries prescribe 2800 ppm fluoride toothpaste (EB: I) – For those 16+ years with active disease prescribe either 2800 ppm or 5000 ppm fluoride toothpaste (EB: I)	
GRADE rating explanation	
GRADE assessment not undertaken due to insufficient information on underpinning evidence. Although evidence were listed in the appendix no direct link to the individual recommendation.	
OVERALL SUMMARY	
This document provides several recommendations for delivering preventive measures available both at the dental office and at home. The recommendations are directed at different age groups/needs. Majority of underpinning studies do not include children with SHCNs; the applicability of the evidence is not always reflected in the level of evidence presented.	

Table 22: Delivering better oral health: an evidence-based toolkit for prevention

Crystal et al. (2017) Use of Silver Diamine Fluoride for Dental Caries Management in Children and Adolescents, Including Those with Special Health Care Needs (169)
https://www.aapd.org/media/policies_guidelines/g_sdf.pdf
Aim: The application of silver diamine fluoride (SDF) to enhance dental caries management n primary teeth

Population and setting	**Intervention/Exposure**	**Intervention/Exposure provider**	**Comparison**	**Outcomes**
Population: Children and adolescents with cavitated caries lesions on primary teeth **Setting**: Dental setting	Application of silver diamine fluoride 38 percent SDF to enhance dental caries management	Health care professionals/ policy makers/ patients	No SDF (other active controls or no treatment)	Caries arrest in primary teeth
Included studies	**Additional criteria**			
Reference one systematic review in 2016 4 RCTs	Evidence was assessed using the GRADE approach.			

Overall results/recommendations	**GRADE evidence certainty rating**
38 percent SDF for the arrest of cavitated caries lesions in primary teeth 24 months; 746 surfaces Risk Ratio (RR) 1.45 (95% CI 0.79 to 2.66) (2 RCTs). Approximately 68 percent (95% CI 9.7 to 97.7) of cavitated caries lesions in primary teeth would be expected to be arrested two years after SDF application (with once or twice a year application).	**Very Low[1]**
≥ 24 months; 3313 surfaces RR 1.42 (95% CI 1.17 to 1.72) (3 RCTs). For 24 months or more, 72 percent versus 50 percent arrested lesions, in absolute terms.	**Very Low[1]**

≥ 30 months; 2567 surfaces RR 1.48 (95% CI 1.32 to 1.66) (1 controlled clinical trials). 48 percent higher (95% CI 32 to 66) success rate in caries lesion arrest compared to the controls semi-annual application. ≥ 24 months1784 surfaces RR 1.25 (95% CI 0.99 to 1.58) (2 RCTs) *all the included trial arms received additional interventions: the application of fluoride such as 0.2 (NaF) rinse every other week in one trial, and the remaining fluoride toothpaste. * After screening the four included clinical trials, none of them include children with disability/needs (GRADE assessment presented in the systematic review)	**Very Low[1]** **Very Low[1]**
GRADE rating explanation	
1. Downgraded due to imprecision and risk of bias.	
OVERALL SUMMARY	
Very low certainty evidence to support the effectiveness 38 percent SDF on caries arrest in primary teeth.	

Table 23: Use of silver diamine fluoride for dental caries management in children and adolescents, including those with special health care needs

Lai et al. (2020) Oral health education and promotion in special needs children: Systematic review and meta-analysis (390)
https://onlinelibrary.wiley.com/doi/10.1111/odi.13731
Aim: improving oral health in children with special needs

Population and setting	**Intervention/Exposure**	**Intervention/Exposure provider**	**Comparison**	**Outcomes**
Population: Children **Setting**: Home, clinic, school, mixed or not specified	• Chlorhexidine • Fluoride-based dentifrices • Powered or modified toothbrushes. • Modified toothbrushes vs manual toothbrushes • Toothbrushing instruction and oral health education v. oral health education only • Video modelling vs control video	Health care professionals	Eight treatment comparisons were identified.	Oral health education and promotion
Included studies	**Additional criteria**			
18 studies qualitative analysis, 11 quantitative analysis	Study designs varied from randomised parallel, cluster crossover trials and non-randomised trails. 14 of the included RCTs had an overall high risk of bias and the remaining 4 unclear risk of bias. (Cochrane Risk of Bias).			
Overall results/recommendations				**GRADE evidence certainty rating**

1. Fluoride v. no fluoride – Fluoride tablets administered in schooling days for three years resulted in large reduction in DMFT index (MD −0.96, 95% CI -1.93 to 0.01) (1 RCT; 142 participants).	**Very low[1,2]**
– Fluoride-containing confectionery (four times daily for three years) had small reduction in the DMFS increment per 100 surfaces (MD −0.45, 95% CI −1.77 to 0.87) (1 RCT; 119 participants).	**Very low [1,2]**
• Chlorhexidine dentifrice v. placebo	
– Chlorhexidine dentifrice vs placebo short-term effect (10–30 days of follow-up) results in a large reduction in the plaque Index in short-term effect (SMD −1.08, 95% CI −1.49 to −0.67) (3 RCTs; 108 participants).	**Low[1]**
– Chlorhexidine dentifrices had no difference on the plaque index in short-term and in the medium-term effect respectively (10–30 days of follow-up) (CHX versus placebo; no fluoride) (SMD −1.43, 95% CI−2.08 to −0.77) (4 NRSs;174; participants) (45 to 60 days of follow-up) (MD −0.61, 95% CI −0.79 to −0.43) (2 NRSs; 113 participants).	**Very low[1,3]**
– Chlorhexidine dentifrices had little to no difference on the Gingival index (the Löe and Silness) in short and medium-term effect respectively (14 to (MD- 0.24, 95% CI −1.21 to 0.73) (2 RCTs; participants 52) (45 to 60 days of follow-up) (MD −0.47, 95% CI −1.08 to 0.14) (2 NRSs; participants 113)	**Very low[1,3]**
• Modified toothbrushes vs manual toothbrushes	
– Modified toothbrushes had a slight reduction on the plaque index in the short-term effect (7 to 28 days of follow-up) (SMD −0.84, 95% CI −1.8 to 0.12) (3; RCTs; 243 participants).	**Very low[1,2,3]**
• Talk and model demonstration based oral hygiene instruction v. video based oral hygiene instruction	

– OHI delivered using the oral health talk and tooth model demonstration versus video demonstration had a slight reduction in the plaque index and gingival index for both short and medium-term follow-up periods. (1 RCT; 100 participants). • Toothbrushing instruction and oral health education v. oral health education only – Additional befit of Toothbrushing instruction and oral health education (OHE) vs OHE (1 RCT; participants 26). • Video modelling vs control video – A small benefit of video modelling on the modified Pods Haley and Haley plaque index in the short and medium term, effect (1 RCT; 20 participants).	**Very low[1,3]** **Very low[1,2]** **Very low[1,2]**
GRADE rating explanation	
1. The evidence downgraded due to risk of bias 2. The evidence downgraded due to imprecision 3. The evidence was downgraded due inconsistency (heterogeneity)	
OVERALL SUMMARY	
Low to very low certainty evidence regarding the effect of chlorhexidine with regard to short-term and long-term reductions in plaque and gingivitis.	

Table 24: Oral health education and promotion in special needs children: systematic review and meta-analysis

Waldron et al. (2019) Oral hygiene interventions for people with intellectual disabilities (389)
https://www.cochranelibrary.com/cdsr/doi/10.1002/14651858.CD012628.pub2/full
Aim: Oral hygiene interventions for people with intellectual disabilities

Population and setting	**Intervention/Exposure**	**Intervention/Exposure provider**	**Comparison**	**Outcomes**
Population: People with intellectual disabilities (children aged 7 to 13 years with Down Syndrome (mild to moderate levels of ID) **Setting**: Residential	Oral hygiene interventions for people with intellectual disabilities	Health care professionals	Placebo/ No additives	Toothbrushing routine Plaque and gingival inflammation levels
Included studies	**Additional criteria**			
2 RCTs and 7 NRS (Another 7 trails included both recruited both children and adult)				

Overall results/recommendations	**GRADE evidence certainty rating**
• **Toothpaste with a plaque-disclosing agent compared to a conventional toothpaste for children with intellectual disabilities** One non-randomised study (40 children with Down Syndrome) reported that toothpaste containing a plaque-disclosing agent when brushing may have reduced plaque and gingival inflammation in the short term (10 days).	**Very Low[1]**

• **Special manual toothbrush compared to conventional manual toothbrush for people with ID (**brushing was carried out by the carers) Gingival index (medium term): mean difference (MD) –12.40, 95% CI –24.31 to –0.49. Plaque (medium term): MD –0.44, 95% CI –0.93 to 0.05; (1 RCT, 18 participants); In the short-term, neither toothbrush showed superiority (GI: MD –0.10, 95% CI –0.77 to 0.57; plaque: MD 0.20, 95% CI –0.45 to 0.85; 1 RCT, 25 participants). • **Electric toothbrush compared to manual toothbrush for people with intellectual disabilities** GI (medium term): MD 0.02, 95% CI –0.06 to 0.09 (2 RCTs, 120 participants). Plaque (medium term): standardised mean difference 0.29, 95% CI –0.07 to 0.65 (2 RCTs, 120 participants). Short-term findings were inconsistent (4 RCTs; low- to very low-certainty evidence). • **Training of carers compared to no training of carers for people with intellectual disabilities** GI (medium term): MD –0.09, 95% CI –0.63 to 0.45 (2 RCTs, 99 participants); Plaque (medium term): MD –0.07, 95% CI –0.26 to 0.13; (2 RCTs, 99 participants). Low-certainty evidence suggested training carers in oral hygiene care had no detectable effect on levels of GI or plaque in the medium term (GI: MD –0.09, 95% CI –0.63 to 0.45; plaque: MD –0.07, 95% CI –0.26 to 0.13; 2 RCTs, 99 participants). One RCT (10 participants) found that training people with ID in oral hygiene care reduced plaque but not GI in the short term (GI: MD –0.28, 95% CI –0.90 to 0.34; plaque: MD –0.47, 95% CI –0.92 to –0.02; very low-certainty evidence). • **Oral hygiene training versus no oral hygiene training of people with intellectual disabilities (3 NRS; 56 participants)**	**Very Low[1]** **Moderate-low[2]** **Low[3]** **Very Low[4]**

The result indicated increase in toothbrushing routine after oral hygiene training (medium and long term (6 weeks to >12 months) with no difference on levels of gingival inflammation or plaque in people with ID.	**Very Low** [5]
• **Training of carers compared to no training of carers for people with intellectual disabilities (2RCTs; 189 participants) Behaviour, attitude and self-efficacy of carers (short and medium term)**	
The two studies were combined in a meta-analysis and showed no evidence of a difference (MD 0.15, 95% CI –0.80 to 1.10y; ChiY = 2.50, df = 1 (P = 0.11); IY = 60%)	**Very Low**[6]
One RCT (29 participants) found that motivating people with ID about oral hygiene by discussing photographs of their teeth with plaque highlighted by a plaque-disclosing agent, did not reduce plaque in the medium term (very low-certainty evidence).	**Very Low**[7]
(GRADE assessment presented in the systematic review)	

GRADE rating explanation

1- This was due to imprecision and unclear risk of bias (single study and small sample).
2- This was due to high risk of bias
3- This was due study design and risk of bias
4- This was due to imprecision and risk of bias (single study and small sample).
5- This was due to study design: based on NRS, with no control groups and all studies were at high risk of bias.
6- This was due to study design as studies at high risk of bias.
7- This was due to imprecision and risk of bias (single study and small sample).

OVERALL SUMMARY
Although some oral hygiene interventions for people with ID show scientific evidence of benefits, what these benefits actually mean for an individual's oral hygiene or oral health is unclear. The certainty of the evidence is mainly low or very low so future research may change our findings.

Table 25: Oral hygiene interventions for people with intellectual disabilities

6.9.2 Summary of evidence

A total of three guidelines were identified and included in this evaluation (162,169,391) (Tables 21-23). The GRADE assessment was not undertaken for the included guidelines except for Crystal et al. (2017), as recommendations were not always linked to specific evidence.

Two of the included guidelines discussed the application of fluoride both at home and at dental office (162,391). The remaining guideline discussed the application of fluoride at the dental office (Crystal et al. 2017). Fluoride interventions recommended included toothpastes, mouth rinses, varnishes and SDF.

Two of the guidelines discussed dietary advice in the documents, but we were not able to GRADE these recommendations as no evidence were linked to them (162,391). As result, the strength of these recommendations is unclear (Table 24,25) (162,391).

Two systematic reviews were identified within literature and included in this evaluation (389,390) (Tables 24 and 25). The study designs included in the systematic reviews varied, despite all reviews evaluating the effectiveness of preventive measures interventions. All underpinning evidence were either at high risk or unclear risk of bias. One review evaluated oral health education and promotion in special needs children (39) (Table 24). The authors included 29 studies with different study design. Waldron et al. (2019) evaluated oral hygiene interventions for people with intellectual disabilities and included two RCTs and seven NRS with children with intellectual disabilities who were less than 18 years old. Another seven trials recruited both children and adults in the same study (34) (Table 25).

- **Prevention measures at home**

Fluoride v. no fluoride

Very low-certainty evidence suggested that fluoride tablets administered in schooling days for three years resulted in large reduction in DMFT index (MD −0.96, 95% CI−1.93 to 0.01) (1 RCT; 142 participants). Fluoride-containing confectionery (four times daily for three years)

had small reduction in the DMFS increment per 100 surfaces (MD −0.45, 95% CI −1.77 to 0.87) (1 RCT; 119 participants) (Table 24).

Toothpaste with a plaque-disclosing agent v. conventional toothpaste

Low-certainty evidence from 1 NRS (40 participants) found that toothpaste with a plaque-disclosing may have a slight benefit in reducing plaque and gingival inflammation in the short term for children with Down Syndrome (Table 25).

Chlorhexidine dentifrice v. placebo

Plaque level

Low certainty evidence from 3 RCTs (108 participants) suggested that Chlorhexidine dentifrice vs placebo in short-term effect (10–30 days of follow-up) results in a large reduction in the plaque Index in short-term effect (SMD −1.08, 95% CI −1.49 to −0.67) (Table 24).

Very low certainty evidence from suggested that Chlorhexidine dentifrices had no difference on the plaque index in short-term and in the medium-term effect respectively (10–30 days of follow-up) (CHX versus placebo; no fluoride) (SMD −1.43, 95% CI−2.08 to −0.77) (4 NRSs;174 participants) (45 to 60 days of follow-up) (MD −0.61, 95% CI −0.79 to −0.43) (2 NRSs; 113 participants) (Table 24).

Gingival inflammation

Very low certainty evidence suggested that Chlorhexidine dentifrices had little to no difference on the Gingival index in short and medium-term effect respectively (14 to (MD- 0.24, 95% CI −1.21 to 0.73) (2 RCTs; participants 52) (45 to 60 days of follow-up) (MD −0.47, 95% CI −1.08 to 0.14) (2 NRSs; participants 113) (Table 24)

Electric toothbrush compared to manual toothbrush

Moderate- and low-certainty evidence found no difference between electric and manual toothbrushes for reducing GI or plaque, respectively, in the medium term (GI: MD 0.02, 95%

CI –0.06 to 0.09; plaque: SMD 0.29, 95% CI –0.07 to 0.65; 2 RCTs, 120 participants). Short-term findings were inconsistent (4 RCTs; low- to very low-certainty evidence) (Table 25).

Special manual toothbrush vs to conventional manual toothbrush

Very low-certainty evidence suggested a special manual toothbrush (the Superbrush) reduced gingival inflammation (GI), and possibly plaque, more than a conventional toothbrush in the medium term (GI: mean difference (MD) –12.40, 95% CI –24.31 to –0.49; plaque: MD –0.44, 95% CI –0.93 to 0.05; 1 RCT, 18 participants); brushing was carried out by the carers. In the short term, neither toothbrush showed superiority (GI: MD –0.10, 95% CI –0.77 to 0.57; plaque: MD 0.20, 95% CI –0.45 to 0.85; 1 RCT, 25 participants) (Table 25).

Modified toothbrushes vs manual toothbrushes

Very low-certainty evidence suggested that Modified toothbrushes had a slight reduction on the plaque index in the short-term effect (7 to 28 days of follow-up) (SMD −0.84, 95% CI −1.8 to 0.12) (3; RCTs; 243 participants) (Table 24).

- **Prevention measures at the dental office**

Fissure Sealants/ topical fluoride/oral health education programmes/oral training (GRADE Not undertaken) (Table 21,22).

Application of SDF 38%

Very low certainty evidence of silver diamine fluoride 38 percent SDF to arrest dental carries in primary teeth (Table 23).

Training of carers compared to no training of carers for people with intellectual disabilities

Low-certainty evidence from 2 RCTs (99 participants) suggested that training carers in oral hygiene care had no detectable effect on levels of GI or plaque in the medium term (GI: MD –0.09, 95% CI –0.63 to 0.45; plaque: MD –0.07, 95% CI –0.26 to 0.13) (Table 25).

Very low-certainty evidence from 1 RCT (10 participants) found that training people with ID in oral hygiene care reduced plaque but not GI in the short term (GI: MD –0.28, 95% CI –0.90 to 0.34; plaque: MD –0.47, 95% CI –0.92 to –0.02;) (Table 25).

Low-certainty evidence from 2 RCTs (189 participants) suggested that training compared to no training of carers had no difference in behaviour, attitude and self-efficacy of carers in the short and the medium term (MD 0.15, 95% CI –0.80 to 1.10) (Table 25).

Oral hygiene training versus no oral hygiene training of people with intellectual disabilities

Low-certainty evidence from 3 NRS (56 participants) found that oral hygiene training resulted in increase in toothbrushing routine in the medium and the long term with no difference on levels of gingival inflammation or plaque in people with ID (Table 25).

6.9.3 Implications for practice and research

While there is evidence of benefit from certain preventive measures for children with SHCNs, the clinical importance of some these interventions is still unclear as evidence were of low to very low certainty.

Very low-certainty evidence suggested that fluoride tablets and fluoride-containing confectionery may reduce decayed dissing and filled teeth. Very low-certainty evidence suggested that using a toothpaste with a plaque-disclosing may reduce plaque and gingival inflammation in the short term. The benefit of using Chlorhexidine dentifrice was inconsistent with moderate to very low certainty evidence in reduction the Plaque Index with no difference on the Gingival Index.

The benefit of using Modified toothbrushes vs manual toothbrushes for children with SHCNs may reduce the plaque level based on very low-certainty evidence. The benefit of using an electric toothbrush compared to a manual toothbrush was inconsistent with moderate and low certainty evidence. Very-low certainty evidence of using of special manual toothbrush (Superbrush) versus the conventional toothbrush as it may in reduce the gingival inflammation and possibly plaque when brushing was carried by caregivers.

Oral hygiene training for carers for people with ID may increase their oral hygiene knowledge based on very low-certainty evidence but not the levels of GI or plaque (low to very low-certainty evidence). Very low evidence of one nonrandomized trail suggested that using a toothpaste with a plaque-disclosing agent may be a benefit to gingival health.

To improve the preventive measures for children with SHCNs, more high-quality evidence of more focused intervention is needed to resolve this problem directly at home and in the dental clinic.

Key implications:

- Basic oral hygiene advise should be reinforced with parents/care givers
- The importance of brushing with a fluoridated toothpaste should be highlighted. Ideally this should be undertaken twice a day. Consideration should be given to the child's individual needs/tolerance of toothbrushing/toothpaste
- If tolerated, further preventive interventions should be considered, as appropriate for the child (e.g., Fluoride varnish may be more readily applied than fissure sealants)
- Support should be provided on ways of reducing sugar in the child's diet

6.10 Discussion

The objective of this review was to identify and assess the effect of evidence-based interventions to overcome access, behavioural and preventive issues of oral care for children with SHCNs. Four reviews and five guidelines were included in this study. The strength of the evidence using GRADE in these reviews were mostly from low to very low certainty. The GRADE assessment was not always feasible for the included guidelines, as recommendations were not always linked to specific evidence.

In general, there is a lack of evidence that focuses purely on access, behavioural management and preventive measure for children with SHCNs in the field of dentistry. As a result, the research community should focus on improving the evidence base to support appropriate future care of children with SHCNs.

The optimal health of children is most likely to be achieved through access to comprehensive care benefits. According to the British Society for Disability and Oral Health (2009), dental treatment could be delivered to patients with disabilities in a variety of different environments, such as a patient's residence, a care home, a community centre or a hospital. Local healthcare centres and public facilities can be helpful in advocating for children with SHCN by providing financial support and trying to resolve any barriers that could limit access to dental care (161).

Evidence shows that the oral health behaviours, attitudes and knowledge of the caregivers of children with SHCNs can either hinder or facilitate the oral health care or oral health promoting behaviours among their children (29). Improving knowledge of caregivers and children with SHCNs could positively impact the oral health outcome for this group. Therefore, it is important for dental professionals to come up with customised oral health training and education programmes for caregivers and children with SHCNs that lay emphasis on the most common challenges that the parents and encounter. In addition, oral health education programmes designed to reinforce as well as maintain healthy behaviours among these children as well as to bring about new, required behaviours such as a more routine dental visit should be introduced to improve their oral health. The concept of reinforcement as well as repetition of instructions related to oral hygiene show significant, short and long-term positive effects (392).

Parents must have a certain level of awareness about the existence of a particular oral health service in the area in order to be able to access it. A review of the literature on oral health of individuals with SHCNs identifies strategies to improve oral health that include improving how community resources are currently organised so that dental care could be made more accessible for everyone, preparing the dental staff to effectively treat this group, and improving empowering individuals and their carrier to improve their oral health (393). The researchers discovered that while many studies were carried out to support these approaches and methods, huge gaps are still evident in the literature when it comes to existence of effective programs.

The lack of awareness among caregivers about preventive oral healthcare measures should be addressed. This is usually a result of their general unawareness about the importance of oral health and dentists often failing to include caregivers/ parents of these children in the process of providing oral care services (364). It is important for the oral care provider to identify as well as address these challenges at an early stage. One effective method is to conduct programmes to increase the awareness of the caregivers about the prevention of oral diseases and to promote routine dental visits and treatment options that are available for their children. These programmes should also educate the parents of these children and empower them to perform daily tooth brushing at home especially after recognising the reported difficulties by parents in this thesis and put alternative oral hygiene aids in place if necessary.

Implementing other preventive measures at home, with the help of oral care provider, is important especially considering parental concerns of scant information about existing preventive techniques and oral health practices. Some children with SHCNs have severe aversions to toothbrushing and toothpaste. In addition, some of children with SHCNs are a hypersensitive to tastes, smells and textures, which can prove to be barriers to toothbrushing. As a result, some parents may end up minimising or avoiding the use of fluoride toothpaste. Alternative methods and techniques for delivering fluoride, if toothpaste is not an option, must be discussed with oral care provider. It is therefore absolutely vital that information about the significance of fluoride, preventative measures for dental diseases, and home oral care is disseminated among caregivers in a clear and effective manner. This will help children with SHCNs to have optimal fluoride exposure and help to prevent or reduce dental diseases.

In addition to oral hygiene behaviours, parents can be encouraged to reduce sugar within a child’s diet. Many children are addicted to sugar and children with SHCNs often have the

additional disadvantage of lacking cognitive abilities to curb overconsumption (394). Children with emotional and learning disabilities often crave foods that are high on sugar and carbohydrates, which can lead to dental issues (394). For children at high risk of dental caries, such as SHCNs, there is a need for parents and caregivers to be more involved in reducing sugar intake (107,395). This is especially pertinent considering the high consumption of sugary foods and drinks among the Saudi population (38). A non-cariogenic diet can be considered for long-term prevention of oral disease. It is crucial to provide dietary guidance as part of public oral health initiatives at the earliest ages for these children. Parents and oral care providers should work together to mitigate the risk of caries through monitoring the frequency of consumption of cariogenic food and drink and by increasing professional and self-care preventive measures. The oral side effects of any medications should also be reviewed; sugar-free medicines should be used whenever possible (396).

In addition, if the dental staff are not adequately trained, challenges are more likely to arise, ultimately resulting in inadequate treatment. Children with SHCNs require coordinated care from the caregiver, dental staff and dentist. They also require services of special clinics, programs, and experienced as well as trained personnel. Therefore, the lack of availability of, and access to proper oral care for special needs patients is something that must be addressed.

Creating greater knowledge as well as skills among the dentists and dental clinic staff members to support children with SHCNs can make access to dental services better. The dental treatment of children who have mild or moderate levels of disability can be carried out in a primary care unit - where their other family members get treated – without much difficulty.

The behaviour management of children with SHCNs is often a challenge to the dental practitioner. Children can display resistant behaviours in different forms as a sign of dental anxiety (160). Such behaviours can interfere with the delivery of safe and comprehensive dental care. Therefore, parents and caregivers need to be present to allow the practitioner to be able to manage unexpected behaviour in the dental clinic (91).

Communication issues among the key barriers in treating children with SHCNs. Dental clinics can use simple approaches to deal with communication barriers for these children. Because some of these children are nonverbal or face difficulty expressing their pain, finding dental issues or caries often depends completely on dental X-rays assisted by the sensitive and

systematic diagnostic methods as well as patient's trust. All staff members at a dental clinic must also be trained to connect and speak with patients with SHCNs and their caregivers in order to make them feel comfortable and enhance their cooperation. Establishing a positive environment to create a long-term relationship between patients and clinicians to help improve oral health is an important task of the dentist for this group of children (89). Poor communication between dentists and children has been reported as a potential cause of dental anxiety during treatment (397). While attending to children with SHCNs, there should be an appropriate way of communication established during each visit. There have to be efforts to communicate effectively with the patient while offering treatment. The parents or caregiver of the child may be required to facilitate communication and provide additional information that the child may not be able to relay (398).

Healthcare professionals such as paediatricians have a key role to play in checking if preventive dental care is being used by a child. They also play an important role in assessing the wellbeing of parents and caregivers. For children who do not use preventive dental care, the healthcare costs can be reduced, and health outcomes can likely be enhanced by making a referral to a local dentist. This will hopefully minimise the emergency dental care needed for these children. Information on caregiver wellbeing can be included in the dental referrals so that the staff at the dental clinic have a proper knowledge of the circumstances of the child's family and can effectively work with the family or caregivers to come up with a personalised oral health strategy for the child and his/her family.

In Saudi Arabia, there appears to be a lack of information about the provision of oral health service for children with SHCNs. The scarcity of credible evidence complicates public health and policy decisions in the country. Without clear and accurate data, it is exceedingly difficult to identify the most pressing concerns in Saudi Arabia that would provide the largest returns if addressed through specific interventions. Future efforts can be redirected to develop and implement policies aimed training and recruiting more specialist healthcare providers for the management of children with SHCNs in order to make them more receptive to the needs of these children (284).

The strategies to meet the dental and oral healthcare needs of children with SHCNs should focus on working closely with the caregivers of the child to develop a personalised preventive programme that fits the age and condition of the child; increasing the child's cooperation in the dental clinic; and increasing access of these children to proper and professional dental care. Bringing about simple changes in the logistics of dental clinics, such as involving children with SHCNs and their parents or caregivers as key partners in enhancing oral hygiene practice and prevention measures for these children will serve as a new foundation for a better future of oral healthcare. Improving the oral health of children with SHCNs is a complex and challenging area. Such oral health initiatives could be linked to wider health improvements but need further testing in Saudi Arabia communities.

6.11 Conclusion

There is limited evidence from studies of children with SHCN to fully inform future provision of oral health care to this population, with available evidence being predominantly of low to very low certainty of evidence. Appropriate training and education programs, aimed at both caregivers and the dental team, on realistic strategies for providing preventive care need to be developed. An evaluation of the workforce is recommended to ensure sufficient oral health professionals are available to meet the needs to children with SHCNs in Saudi Arabia. It is likely that caregivers and the dental team need to work more closely to ensure individualized care plans, incorporating known, effective preventative interventions as appropriate for each child with SHCNs. The development of national guidelines on the delivery of care for this vulnerable population are recommended.

CHAPTER SEVEN

DISCUSSION

7.1 General Discussion and Future Work

This final chapter describes the strengths and shortcomings of the presented work and explores areas for future research. This thesis has involved evaluating recommendations on oral care management; extraction of relevant information from the evidence referenced in published guidelines; assessing different interventions to increase the acceptance of local anaesthesia (LA); investigating parental perceptions of delivered oral care; discussions around the identified barriers in the provision of oral care; and the formulation of recommendation for children with SHCNs. This chapter does not aim to repeat statements that have been mentioned in the previous chapters, but instead seeks to address issues identified within the body of the thesis. Areas of interest for future work surrounding oral care for children with SHCNs will also be outlined.

7.2 Issues highlighted through the appraisal of clinical guidelines

In Chapter Three it was shown that the current guidelines that exist for oral care for children with SHCNs are often of low quality, with limitations in guideline development processes and critical appraisal of the literature. Systematic reviews were undertaken by many of the guideline developers; however these reviews were not rigorous enough. Moreover, most reviews did not seem to entail an assessment or appraisal of the different aspects of methodology with regards to the cited evidence. Additionally, the guideline developers failed to cite high-quality evidence such as systematic reviews with the exception of two of the included guidelines. In addition, the majority of guidelines addressed many different aspects of oral care management for children with SHCNs with ambiguous and vague recommendations. All three assessors concurred that only one of the guidelines met the standards of AGREE II tool, evidently shedding light on the poor quality of guidelines available for oral care management for children with SHCNs.

As with any evidence, it is important to critically appraise clinical guidelines to understand whether or not they are reliable enough to be used, and so the AGREE II tool, the most widely

used and recognised among the healthcare researchers, recognised as an internationally accepted standard, was used for guideline appraisal (173). However, the use of this instrument is not without its limitations. A major limitation is that AGREE II does not assess the robustness of the evidence base used to formulate the resulting guidelines. One of the key aspects of a guideline is the underpinning evidence supporting it, but the AGREE II tool does not evaluate the appropriateness or the robustness of this evidence.

As guidelines are often used by individuals who do not possess a working knowledge of the literature in a specific domain or who lack a comprehensive understanding of research methodology or appraisal of evidence, these individuals may blindly follow the guidelines believing them to be more accurate and dependable than they are. The use of unverified terminologies such as 'systematic review' and 'evidence-based' may mislead practitioners, leading to a proliferation of poor clinical practices that may result in sub-optimal treatment. In addition, those practitioners whose expertise or acquaintance with the literature causes them to rightly disregard such poorly informed guidelines may also lose confidence in other, high-quality guidelines.

Guidelines that are developed through the employment of rigorous methods are more likely to offer comprehensive and valid recommendations. However, there is a possibility that the rigour and evidence base of guideline development may differ as per the clinical area. For certain clinical issues, a large volume of high-quality literature may exist that needs to be identified, properly assessed, appraised and interpreted before any guideline recommendations can be formulated. Any high-quality evidence must be incorporated into the process of guideline development.

Conversely, for some clinical topics, there may be little literature available, and regardless of the appropriateness of search methods or strategies of appraisal, the final suggestions may not be different from those formulated through the use of expert opinion. In the same way, recommendations that are formulated through the use of systematic methodologies but are underpinned by poor-quality evidence may not fundamentally be any better than the recommendations that are developed through the use of formal consensus. It can be argued that one cannot be certain about the quality or volume of existing evidence without proper documentation, systematic identification and proper evaluation of research literature. It is therefore vital that authors of guidelines be transparent about the nature of the evidence

supporting each recommendation and provide caveats to ensure that recommendations based on poor-quality evidence are not misconstrued as best practice. In addition, when recommendations in guidelines are being formulated in the absence of evidence for children with SHCNs, we recommend that a clear statement be issued by guidelines developers to acknowledge the limitations of the underpinning evidence and to discuss the applicability of evidence extrapolated from other populations/settings.

7.3 Issues highlighted by the systematic review of acceptance of LA

The systematic review of interventions to increase acceptance of local anaesthesia conducted in Chapter Four highlighted the different metrics used for measurement of outcomes in the studies. There was, for example, a large variation in the outcomes evaluated and the time points of evaluation that made it very difficult to synthesise the studies and interpret the results in any meaningful way. Moreover, different types of measurement scales with different interpretations were also used by the researchers to report on outcomes. The lack of clarity on how and when the outcomes were evaluated, with a wide variation between trials on the way in which the outcomes were reported made it impossible to pool or standardise the data. This thesis found that these scales are selected, used and interpreted inconsistently, even in similar clinical contexts. Furthermore, study methods were often poorly reported, explained or justified, making it difficult to draw a comparison between the findings of similar studies.

Research studies that evaluate outcomes that are not of importance to end-users will not be preferred or used, resulting in wastage of limited healthcare research resources. In clinical trials, decision-making relating to treatment or clinical care do not get improved by measuring outcomes that are of little importance to clinicians or patients, or that are difficult to implement in clinical care. It is important to select an appropriate outcome for randomised controlled trials in order to ensure the external validity as well as the applicability of the findings (399).

There is a need to develop core outcome sets that are disease- or condition-specific in order to come up with well-informed decisions related to healthcare interventions and to make sure that the outcomes are evaluated as well as reported in the same way (400). This will standardise the process of carrying out and reporting clinical trials. Contrary to the idea of reporting a large number of outcomes, it can be argued that focusing on a small number of outcomes and

developing a comprehensive report on them comprising all data enables reviewers or assessors to pool data effectively across studies and is more relevant to stakeholders. A core set of outcomes has been suggested by the Core Outcome Measures in Effectiveness Trials (COMET) initiative (401). Laying emphasis on the outcomes that have been found to be critical to stakeholders should result in more valuable and relevant research, which should ultimately feed into guidelines and lead to enhanced clinical practice and patient outcomes.

Heterogeneity is a major issue stemming from inconsistencies in the consideration and understanding of outcomes in clinical research. Heterogeneity makes it challenging to compare and synthesise research with a similar focus, such as when carrying out systematic reviews (401). There is a need to reach an agreement regarding the ideal index that is to be used for multiple clinical outcomes to ensure that the comparisons drawn between studies are valid and relevant. In addition, the indices should not be modified in a significant way, with only validated ones being used in clinical trials. Hence, it is very important to consider the choice of outcome measures when evaluating the effects of interventions before setting up a clinical trial. Moreover, the PICO framework should be used by researchers for the clarification and articulation of answerable research questions (population, intervention, comparison, outcome) (402). Chapter Four highlights that robust methodology must be employed to ensure better reporting of trials in this area. In particular, exploration of the reporting of paediatric chronic pain assessments warrants further investigation.

Inadequate reporting has been a well-known issue for almost four decades in randomised controlled trials (403). Many difficulties were encountered in attempting to assess the quality of randomised trials in the early nineties when it was found that fundamental methodological information was not reported on regularly by authors (404). This resulted in attempts to standardise the reporting of clinical trials, leading to the formulation of the first Consolidated Standards of Reporting Trials (CONSORT) statement being published in 1996 (404), which was later modified in 2010.

A priori trial registration, as suggested in the CONSORT statement informs assessors about entire components of the trial (PICO) that include the proposed primary outcome, thereby helping to avoid selective outcome reporting and research waste. Selective outcomes arise when more than one outcome is evaluated but not all outcomes are reported on. This can be detected when a protocol is published and compared with the final report (405). This improves

transparency and reduces the risk of bias. Indeed, protocol publication has been stated by the Declaration of Helsinki as imperative prior to the recruitment of the first subject (406). In addition, the failure of outcomes to be consistent across each link in the chain of evidence can take place if trialists and reviewers are not aware or inadequately interacting with important elements of the related evidence (407).Taking the aforementioned considerations into account can limit avoidable research waste.

Moreover, a failure to comprehensively report clinical trials can lead to many challenges and difficulties at the stage of evidence synthesis. When the reporting of trials is not standardised, it becomes very difficult to assess the quality of the evidence or to know if the trial has been conducted properly. It can also signal issues in research conduct, raising questions about the validity of results. This ultimately has consequences on the risk of bias and quality of evidence assessment in secondary research such as systematic reviews and guidelines.

7.4 Lack of literature addressing children with SHCNs

Another limitation of the evidence base highlighted throughout the thesis was the lack of studies pertaining to children with SHCNs in paediatric dentistry. The external validity of trials can be called into question due to the exclusion of certain groups in research. This is even more important when certain groups of individuals are systematically excluded from those clinical trials (408,409). External validity refers to the extent to which the results of a study can be generalised to other groups or circumstances. This has resulted in major research funders such as the UK National Institute for Health Research (NIHR), undertaking projects to tackle the challenges in conducting health research with underrepresented groups and to introduce reviews of the justification for, and the suitability of, the criteria for inclusion and exclusion in health research (e.g. NIHR INCLUDE) (410). It is important to ensure fair representation of all individuals in health research in order to improve outcomes for all. It is also important to acknowledge that individuals with SHCNs not only have the right to quality, evidence-based treatment but that they can also make significant contributions to the betterment of their own lives by actively participating in research (411).

Regardless of some of the trends toward the inclusion of more minority groups in research, individuals with SHCNs are still excluded from most areas of health research (412). At the same time, this group is among the greatest prospective beneficiaries of healthcare services.

One of the reasons why this group is excluded from research is the exceedingly strict criteria for inclusion. Feldman et al. (2014), explored the rate of exclusion for children with SHCNs from developmental research published in high-impact journals and found that around 67% of articles explicitly excluded children with SHCNs (408). The rate was even higher, approximately 90%, when the studies consisted of articles in which disability were not explicitly mentioned, with the assumption that no discussion or inclusion meant exclusion. In addition, it was determined by expert assessors that children with disabilities or needs were excluded in 50% of the studies in which they could have been included without specific accommodations. It was determined by the authors that children with at least one type of disability or need could have been included in over 60% of research when accommodations were made, without compromising the reliability and integrity of the research (408).

High-quality evidence that includes individuals with SHCNs is important to guide decisions related to the prevention and treatment of health conditions. It can be very harmful if people belonging to a vulnerable group with a high chance of suffering from certain health issues are excluded from taking part in research that can benefit them. Excluding individuals at higher risk of health problems research can be detrimental to their health in the long-term and as a result, a greater loss may arise. Journal publishers and research ethics committees should consider implementing education initiatives, procedures and policies to promote balanced participation and fairness in health research and safeguarding to protect marginalised communities. All societal groups, no matter what their perceived abilities are, have the right to equal representation in health research.

There are many challenges in improving the participation of children with SHCNs in oral health research. Some of these challenges include overestimation of disability or needs by researchers and ethics committees, discomfort of researchers, underestimation of competence, inexperience in dealing with disabled individuals, and/or concerns that research integrity will be jeopardised or that it will be too costly to accommodate this group (408). In addition, there may be methodological challenges, which include the complexities of developing or adjusting interventions (assessing interventions as well as coming up with a common protocol that can be applied to different areas), participant recruitment challenges and disagreements over participation between caregivers and individuals with SHCNs (413,414). This can be further intensified by the current challenges raised in terms of the lack of validated and/or appropriate outcome measures for use in clinical trials involving children with SHCNs (415). Overall,

many systemic barriers exist to the inclusion of children with SHCNs in oral health research; nonetheless, clinicians and researchers must start thinking of simple yet innovative methods to resolve some of these issues (408).

One of the ways researchers can do this is by seeking advice from individuals with disabilities or needs and from inclusion experts to devise accessible research design as required. Knowledge exchange activities, research protocols, as well as assent and consent procedures, for example, incorporating audio-visual aids, computer-assisted technology, oral and alternative communication methods, and simplified language enable these individuals to participate in research (416–418).

Many researchers attain substitute consent and simple assessment procedures can be implemented with adaptations to research methods (such as simplification of questionnaire or observational scales). All of the required modifications can be tested before the study commences to ensure that research integrity is not affected (408). Furthermore, simple comprehension questions in the preferred mode of communication of the participant can be included in the consent process to confirm informed consent, for example (416). The risks of preventing vulnerable individuals from taking part in research should be considered by ethics boards to identify design considerations, consent procedures as well as safeguards that would safely enable the inclusion of individuals with SHCNs. Systematic assessment of attrition rates in clinical studies as well as large cohort studies aimed at determining the impact of overly strict criteria for inclusion or exclusion, as well as that of inaccessibility is required to document the need for inclusion of a higher number of individuals with SHCNs in clinical, longitudinal, and epidemiological research. Initiatives such as the International Classification of Functioning, Disability and Health (ICF) Core Sets by the World Health Organisation that seek to distinguish and recognise the most important data that should be included in clinical studies that have targeted this population and other organisations should follow thorough (419).

It is expected that it would take time to develop as well as promote robust research in the field of paediatric dentistry for children with SHCNs. However, this task is not impossible by any means despite the various challenges that exist, if there is consistent and continuous multidisciplinary professional collaboration, teamwork and enthusiasm among health agencies and academic institutions. Every effort should be made to ensure that children with SHCNs are not excluded from research, especially when these children will likely benefit from it.

The Uniform Requirements for Manuscripts Submitted to Biomedical Journals (URMs) as well as the CONSORT guidelines have been key contributions in enhancing the transparency of randomised controlled trials (404,420). Further effort should be made to address unjustified exclusion criteria as well as to improve adherence to these guidelines on reporting in clinical research (421). When exclusions are necessary, each criterion should be clearly justified within the study.

7.5 Issues highlighted in the qualitative study

The use of thematic analysis for analysis used in Chapter Five for the identification, evaluation and reporting of themes from the interviews proved to be a sound methodological decision. However, there were also some limitations related to translations in this study. All interviews were conducted in Arabic, and then translated by the principal researcher into the English language. There is a possibility that the nuances or the connotations of some participant responses may have been lost or altered during translation. It is also possible that the translation process allowed for the introduction of researcher bias. The researchers made every attempt to make sure that each interview was translated verbatim to English to ensure that the intended meaning was not lost during this process. In addition, assistance with validation as well as translation was provided by another PhD student who is fluent in both English and Arabic and has experience in the field of oral health research.

Prior to the COVID-19 pandemic research approval was based on face-to-face interviews. In order to comply with "social distancing" mandates and governmental policies during these unprecedented circumstances, methods were adopted to use telephone or videoconference platforms. Face-to-face interviews, however, may have been more effective than videoconference or telephone interviews as the limited or lack of non-verbal cues may have negatively impacted data quality (422). Some drawbacks of telephone interviews include difficulty in maintaining the engagement and cooperation of the participants, high chances of miscommunication or frustration (for example, interviewees may find it difficult to hear or understand the questions), the chances of a third party being present when the telephone interviews are being conducted, and the absence of visual cues which can hinder communication and understanding (423).

Conversely, however, the qualitative interviews permitted greater participant anonymity and hence may have encouraged more honest answers (423,424). Telephone interviews also offered the interviewees a greater sense of comfort as in-person meeting was not required. In addition, these interviews also enabled the interviewees to tune in at a time and place of their choosing. Moreover, the main researcher was able to write down responses discreetly, and thus participants were able to give their opinions freely and with minimal distraction. Since the interviewees were unable to see the researchers and/or their facial expressions in-person, their responses were not impacted or influenced in any way (423). Taking the research ethics into consideration, there were no major differences between the telephone interviews and face-to-face interviews as both approaches were as per the ethical procedures, ensured anonymity, gained informed consent and ensured confidentiality as well as privacy of the participants (425). Future work may wish to use different data-gathering methods with face-to-face interviews to compare and contrast with our findings.

It should also be considered that it may have been challenging for the research participants to accurately recall the time and the experience of an event. The researcher therefore used two timeframes to ask participants separately about any oral care experiences that had an impact on their children. One was confined to issues encountered by the children in the past year while the other did not have a specific timeframe (issues that the children had experienced at any point in time).

Another area of consideration that may influence the usefulness and interpretation of the qualitative study was the inclusion of children between the ages of 7 and 11. This might have affected parents' reports of issues related to the oral health of their children since children of this age group are expected to have newly erupted permanent teeth or mixed dentition, and hence, the chances of a dental diseases might be expected to be different or lower among these children. Children with multiple or severe disabilities and/or needs were excluded in the sampling method in the qualitative chapter and consequently this could obscure crucial details relevant to the study topics. However, since the research was considered to be a step in gathering and understanding the perceptions of parents of Children with SHCNs in primary dental care units, the researchers thought that different perspectives and dimensions of need may arise if children with severe or multiple disabilities or needs were included in the research sample. In addition, it is important to acknowledge that the research was conducted on only 12 parents whose oral health related experiences can differ as per the reason for visiting a dental

clinic and the nature of the needs of their children. Furthermore, based on the research team experiences and the literature, (343,426), we estimated that the recruitment of 12 to 20 parents and caregivers of children with SHCNs would achieve data saturation and informational redundancy. After interviewing 12 parents, the analysis of the new data did not yield any new themes or ideas due to repetition of findings and data gathering was ended. As a consequence, the findings of this research cannot be widely generalised.

The researchers did not request detailed information about the demographics and various socioeconomic factors that could have allowed for the data to analysed in greater depth. Because both general and oral health is impacted by socioeconomic factors, this lack of stratification is another area of limitation of Chapter Five. Whilst in our study we were able to report on parents' perception and experience of oral care delivery, oral health practices and preventive measures for their children, there needs to be further study of a more representative sample of participants with detailed demographic details conducted within Saudi Arabia.

The nature of the participants and the social context in which the research was conducted should also be considered. Conducting in-depth interviews is not a common practice in Saudi Arabia – a country in which family privacy is considered an important issue. Personal issues are not commonly talked about in a conservative country like Saudi Arabia. It is especially challenging for a male researcher to interview women and expect them to open up and talk about their experiences as conversations between individuals of the opposite gender who are not related are socially discouraged. Moreover, parents in Saudi Arabia do not like to talk about the needs or disability of their children, sharing their views and expressing their opinions candidly can be a challenging task and can be seen as a sign of weakness or admission of neglect (427). The depth and breadth of the data gathered may be affected by these factors, and there may be other factors that have influenced the participants to not express themselves freely.

Another area of limitation in this study is that a broader range of key stakeholders such as oral care providers and policymakers were not included in the study. Including them would have potentially enabled the researchers to gather more comprehensive views and perceptions about the existing provision of oral care and preventive measures for children with SHCNs. As such, future research should focus on children with severe or multiple disabilities or needs and

include key stakeholders through the use of more inclusive methods to gather a deeper insight into the oral care experiences among these children.

Another area of concern is using parents as a proxy for understanding the experiences of children with SHCNs. Some children with mild to moderate needs may have been able to provide a valid report about their oral care experiences themselves. However, the study was mainly aimed at exploring the perceptions of the parents of Children with SHCNs, thereby offering a more comprehensive view of the concerns that might not be recorded through the reports of these children due to impaired cognitive abilities. It is also important to view the perceptions of parents as a base upon which a fuller picture can be constructed. Accordingly, this research was directed towards parental perceptions with the assumption that they are the primary caretakers for these children and therefore possess knowledge of their well-being as well as that of their health status. Future work may expand on the current analysis by incorporating the perceptions of children with SHCNs in the analysis and assessing if results differ from those reported by the parents in Chapter Five.

Conclusions

Evidence-based practice has become very popular and is widely adopted across many disciplines (171). It has significantly enhanced the conduct and reporting of clinical guidelines, systematic reviews and clinical trials. It will be advantageous for all stakeholders to work collaboratively to develop a comprehensive and meticulous evidence base that can be used to build clinical guidelines that are directly applicable to children with SHCNs.

Researchers should study existing protocols before embarking on new research projects and should be encouraged to approach those who conduct similar research projects in order to collaborate and ensure relevant research outcomes. The distinct but complementary skills of clinicians, patients, statisticians, methodologists and information specialists working together when conducting evidence-based research must be recognised to make sure that feedback is relevant and truly evidence-based.

The barriers to the provision of oral care that have been detailed in this thesis document the fact that it is vitally important to implement measures to ensure that appropriate health care facilities are available to children with SHCNs in Saudi Arabia. In addition, dentists should have proper knowledge and training in order to adapt their practices so that the needs of these individuals in terms of oral health care can be met. Appropriate education programmes related to oral health should be provided to children with SHCNs as well as their families to prepare them for dental appointments.

Both '*Clinical Guidelines and Integrated Care Pathways for the Oral Health of People with Learning Disabilities*' as well as '*Valuing People'* emphasise the need for an integrated multi-disciplinary method and strategy to care for children with SHCNs (18,162). Providing children with SHCNs with high quality dental care may necessitate active liaison with healthcare facilitators and require work across professions to make sure that their oral health is also given importance. Coordinated efforts by dental professionals are needed to provide dental health education and preventive interventions for these children.

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APPENDIX 1: Guideline's appraisal- electronic search strategies

MEDLINE (OVID) search strategy

1. Disabilities.mp.
2. special healthcare need.mp.
3. special health need.mp.
4. exp Disabled Children/
5. exp Intellectual Disability/
6. exp Developmental Disabilities/
7. medical compromised.mp.
8. medical ill.mp.
9. limitation.mp.
10. or/1-9
11. exp Child/
12. children.mp.
13. exp Child, Preschool/
14. exp Adolescent/
15. exp Young Adult/
16. or/11-15
17. 10 and 16
18. (oral adj6 care$).ti,ab.
19. exp Dental Care/
20. Management.mp.
21. Treatment.mp.
22. ((oral or mouth) adj5 care).ti,ab.
23. or/18-22
24. 17 and 23
25. exp Consensus Development Conference/
26. exp Guideline/
27. exp Guidelines as Topic/
28. exp Practice Guideline/
29. Practice Guidelines as Topic/
30. Health Planning Guidelines/

31. (standards or guideline or guidelines or guidance$).ti,kf,kw.
32. ((practice or treatment$ or clinical) adj guideline$).ab.
33. or/25-32
34. 24 and 33

APPENDIX 2: Local anaesthetic review – electronic search strategies

1 Cochrane Oral Health's Trials Register search strategy

1 (local and (anesthetic* or anaesthetic* or anesthesia or anaesthesia)):ti,ab
2 (lidocaine or lignocaine or xylocaine):ti,ab
3 (carticain* or articain*):ti,ab
4 (prilocain* or citanest* or propitocain* or xylonest):ti,ab
5 (bupivacain* or buvacaina or carbostesin or dolanaest or marcain* or sensorcain* or svedocain*):ti,ab
6 #1 or #2 or #3 or #4 or #5
7 (child* or infant* or adolescen* or teenage* or preteen* or pre-teen*):ti,ab
8 #6 and #7

2 Cochrane Central Register of Controlled Trials (CENTRAL) search strategy

#1 [mh Dentistry]
#2 (dental* or dentist*)
#3 (oral near/5 surg*)
#4 (orthodontic* or pulpotom* or pulpect* or endodont* or "pulp cap*")
#5 ((dental or tooth or teeth or molar* or incisor* or cuspid* or bicuspid*) near/5 (fill* or restor* or extract* or remov* or "cavity prep*" or caries or carious or decay*))
#6 ("root canal" and (therap* or treat*))
#7 (tooth near/3 replant*)
#8 {or #1-#7}
#9 [mh ^"Anesthetics, local"]
#10 [mh ^"Anesthesia, local"]
#11 (local near/5 (anesthetic* or anaesthetic* or anesthesia or anaesthesia))
#12 [mh ^Lidocaine]
#13 (lidocaine or lignocaine or xylocaine)
#14 [mh ^Carticaine]
#15 (carticain* or articain*)
#16 [mh ^Prilocaine]
#17 (prilocain* or citanest* or propitocain* or xylonest)
#18 [mh ^Bupivacaine]
#19 (bupivacain* or buvacaina or carbostesin or dolanaest or marcain* or sensorcain* or svedocain*)
#20 {or #9-#19}
#21 [mh Child]
#22 [mh Infant]
#23 [mh Adolescent]
#24 (child* or infant* or adolescen* or teenage* or preteen* or pre-teen*)
#25 (pediatric* or paediatric*)
#26 [mh ^"Dental care for children"]
#27 {or #21-#26}
#28 #8 and #20 and #27

3 MEDLINE (OVID) search strategy

1. exp DENTISTRY/
2. (dental$ or dentist$).ti,ab.
3. (oral adj5 surg$).ti,ab.
4. (orthodontic$ or pulpotom$ or pulpect$ or endodont$ or "pulp cap$").mp.
5. ((dental or tooth or teeth or molar$ or incisor$ or cuspid$ or bicuspid$) adj5 (fill$ or restor$ or extract$ or remov$ or "cavity prep$" or caries or carious or decay$)).mp.
6. (root canal and (therap$ or treat$)).mp.
7. (tooth adj3 replant$).mp.
8. or/1-7
9. Anesthetics, Local/
10. Anesthesia, Local/
11. (local adj5 (anesthetic$ or anaesthetic$ or anesthesia or anaesthesia)).mp.
12. Lidocaine/
13. (lidocaine or lignocaine or xylocaine).mp.
14. Carticaine/
15. (carticain$ or articain$).mp.
16. Prilocaine/
17. (prilocain$ or citanest$ or propitocain$ or xylonest).mp.
18. Bupivacaine/
19. (bupivacain$ or buvacaina or carbostesin or dolanaest or marcain$ or sensorcain$ or svedocain$).mp.
20. or/9-19
21. exp Child/
22. Infant/
23. Adolescent/
24. (child$ or infant$ or adolescen$ or teenage$ or preteen$ or pre-teen$).mp.
25. (pediatric$ or paediatric$).mp.
26. Dental care for children/
27. or/21-26
28. 8 and 20 and 27

The above subject search was linked with the Cochrane Highly Sensitive Search Strategy (CHSSS) for identifying randomised trials (RCTs) in MEDLINE: sensitivity maximising version (2008 revision) as referenced in Chapter 6.4.11.1 and detailed in box 6.4.c of the *Cochrane Handbook for Systematic Reviews of Interventions,* Version 5.1.0 (updated March 2011) (Higgins 2011).

1. randomized controlled trial.pt.
2. controlled clinical trial.pt.
3. randomized.ab.
4. placebo.ab.
5. drug therapy.fs.
6. randomly.ab.
7. trial.ab.
8. groups.ab.
9. or/1-8
10. exp animals/ not humans.sh.
11. 9 not 10

4 Embase (OVID) search strategy

1. exp DENTISTRY/
2. (dental$ or dentist$).ti,ab.
3. (oral adj5 surg$).ti,ab.
4. (orthodontic$ or pulpotom$ or pulpect$ or endodont$ or "pulp cap$").mp.
5. ((dental or tooth or teeth or molar$) adj5 (fill$ or restor$ or extract$ or remov$ or "cavity prep$" or caries or carious or decay$)).mp.
6. (root canal and (therap$ or treat$)).mp.
7. (tooth adj3 replant$).mp.
8. or/1-7
9. Local anesthetic agent/
10. Local anesthesia/
11. (local adj5 (anesthetic$ or anaesthetic$ or anesthesia or anaesthesia)).mp.
12. Lidocaine/
13. (lidocaine or lignocaine or xylocaine).mp.
14. Articaine/
15. (carticain$ or articain$).mp.
16. Prilocaine/
17. (prilocain$ or citanest$ or propitocain$ or xylonest).mp.
18. Bupivacaine/
19. (bupivacain$ or buvacaina or carbostesin or dolanaest or marcain$ or sensorcain$ or svedocain$).mp.
20. or/9-19
21. exp Child/
22. Infant/
23. Adolescent/
24. (child$ or infant$ or adolescen$ or teenage$ or preteen$ or pre-teen$).mp.
25. (pediatric$ or paediatric$).mp.
26. or/21-25
27. 8 and 20 and 26

The above subject search was linked to the Cochrane Oral Health filter for identifying RCTs in Embase via OVID:

1. random$.ti,ab.
2. factorial$.ti,ab.
3. (crossover$ or cross over$ or cross-over$).ti,ab.
4. placebo$.ti,ab.
5. (doubl$ adj blind$).ti,ab.
6. (singl$ adj blind$).ti,ab.
7. assign$.ti,ab.
8. allocat$.ti,ab.
9. volunteer$.ti,ab.
10. CROSSOVER PROCEDURE.sh.
11. DOUBLE-BLIND PROCEDURE.sh.
12. RANDOMIZED CONTROLLED TRIAL.sh.
13. SINGLE BLIND PROCEDURE.sh.
14. or/1-13

15. (exp animal/ or animal.hw. or nonhuman/) not (exp human/ or human cell/ or (human or humans).ti.)
16. 14 NOT 15

5 Web of Science search strategy

12 #7 and #10 and #11
11 TS=(child* or infant* or adolescen* or teenage* or preteen* or pre-teen*)
10 #8 or #9
9 TS=(lidocaine or lignocaine or xylocaine or carticain* or articain* or prilocain* or citanest* or propitocain* or xylonest or bupivacain* or buvacaina or carbostesin or dolanaest or marcain* or sensorcain* or svedocain*)
8 TS=(local and (anesthetic* or anaesthetic* or anesthesia or anaesthesia))
7 #1 or #2 or #3 or #4 or #5 or #6
6 TS=(tooth AND replant*)
5 TS=("root canal" and (therap* or treat*))
4 TS=((dental or tooth or teeth or molar* or incisor* or cuspid* or bicuspid*) AND (fill* or restor* or extract* or remov* or "cavity prep*" or caries or carious or decay*))
3 TS=(orthodontic* or pulpotom* or pulpect* or endodont* or "pulp cap*")
2 TS=("oral surgery")
1 TS=(dentist* or dental*)

6 US National Institutes of Health Ongoing Trials Register ClinicalTrials.gov search strategy

dental and anesthesia and child and accept

dental and anesthesia and child and behavior

7 metaRegister of Controlled Trials (mRCT) search strategy

dental and anaesthesia and child

dental and anesthesia and child

8 World Health Organization International Clinical Trials Registry Platform search strategy

dental and anaesthesia and child

dental and anesthesia and child

APPENDIX 3: Characteristics of studies and risk of bias tables

Characteristics of included studies

Abdelmoniem 2016

Methods	Study design: randomised trial, parallel Location: Egypt Number of centres: 1 Setting: hospital/university Recruitment period: not reported
Participants	Inclusion criteria: positive or definitely positive Frankl scale Exclusion criteria: not reported Number of participants randomised: 90 Number of participants evaluated: 90 Number of males/ females: not reported Age: Group 1: 7.18 ± 1.94 years; Group 2: 7.02 ± 2.2 years; Group 3: 7.65 ± 1.8 years
Interventions	Group 1: passive distraction (listening to the same song on headphones); during LA delivery Group 2: active distraction (moving legs up and down alternatively as a game); during LA delivery
Outcomes	Pain perception during administration of local anaesthesia: assessed by the Sound, Eyes, and Motor (SEM) scale and Wong-Baker Faces Pain Rating Scale Observed pain: assessed by Sound, Eyes, and Motor (SEM) scale. It is divided into 2 categories of comfort and discomfort
Notes	Declarations of interest: not reported Sample size calculation performed and discussed No reliability calculations

Risk of bias table

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	Not enough information on the randomisation procedure Quote: "The study sample was randomly divided into three equal groups 30 children each"
Allocation concealment (selection bias)	Unclear risk	Not reported or discussed
Blinding of participants and personnel (performance bias)	Unclear risk	Not reported

Blinding of outcome assessment (detection bias)	High risk	Not reported, although authors discuss one clinician performed the treatment and another one evaluated the child
Incomplete outcome data (attrition bias)	Low risk	No excluded patients
Selective reporting (reporting bias)	Low risk	All recorded outcomes were reported on within the results section
Other bias	Low risk	No further bias

Al-Halabi 2018

Methods	Study design: randomised trial, parallel Location: Syria Number of centres: 1 Setting: university Recruitment period: April to October 2017
Participants	Inclusion criteria: age group between 6 and 10 years, no previous dental experience, no systemic or mental comorbidities, definitely positive or positive ratings on the Frankl scale; needed administration of LA Exclusion criteria: not defined Number of participants randomised: 102 Number of participants evaluated: 101 (1 patient was excluded due to behavioural problems) Number of males/females: 60 boys, 41 girls Mean age (years): 7.4
Interventions	Group 1: IANB administered using audiovisual eyeglasses virtual reality box (VR Box) and wireless headphone. Cartoon played (chosen by child) Group 2: IANB administered using tablet device and wireless headphone. Cartoon played (chosen by child) Group 3 (control group): IANB administered with basic behaviour guidance techniques and without distraction aids
Outcomes	Pain perception during administration of LA: Wong-Baker Faces Scale. Self-assessment after LA, ranging from 0 (no pain) to 5 (hurts the worst) Observed pain: Face, Legs, Activity, Cry, Consolability scale (FLACC scale). Validated in the Syrian population. Ranging from 0 (no expression, movement, no crying and content) to 2 (frequent to constant quivering, crying, kicking, jerking/rigid, difficult to console) Pulse rate: measured when patient was first seated and immediately after LA. Difference between measurements was calculated
Notes	Declarations of interest: not reported Sample size calculation performed and discussed

	No discussion whether the Wong-Baker Faces Scale was adapted as normal rating ranges from 0 to 10 and in this study authors discussed they ranged from 0 to 5

Risk of bias table

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Quote: "A random allocation list was generated using a randomisation website 'Random.org'"
Allocation concealment (selection bias)	Unclear risk	No discussion regarding allocation concealment is presented
Blinding of participants and personnel (performance bias)	High risk	Children not blinded. Not possible to blind operator either – although not discussed
Blinding of outcome assessment (detection bias)	High risk	Quote: "inability of blinding the external investigator from child's use of the AV eyeglasses 'VR Box'"
Incomplete outcome data (attrition bias)	High risk	Numbers of patients not presented on table, no CONSORT flow chart. Discussion that 1 participant was removed due to behaviour issues but no discussion to which group he belonged and on which phase was the treatment discontinued
Selective reporting (reporting bias)	Unclear risk	Values for each measurement were not presented as only 1 combined value was given. Unsure these scales can be combined. Not possible to compare with other studies
Other bias	High risk	No discussion of whether duration of LA delivery was controlled for Not discussed how many operators and what was their level of training Not discussed how many observers, level of training and if they were calibrated The authors stated that the size of audiovisual eyeglasses 'VR Box' was big for many children without further explanation

Al-Khotani 2016

Methods	Study design: prospective randomised controlled trial, parallel Location: Saudi Arabia Number of centres: 1

	Setting: university hospital Recruitment period: September 2007 to May 2008 Funding source: not discussed
Participants	Inclusion criteria: general good health, no previous dental experience involving LA administration for the last 2 years and restorative treatment required under LA Exclusion criteria: previous unpleasant experience in medical setting or known dental phobia as reported in the medical records, need for pharmacological management to co-operate or medical disability such as the history of seizures or convulsion disorders, nystagmus, vertigo or equilibrium disorders, eye problems and autism Number of participants randomised: 56 Number of participants evaluated: 56 Number of males/females: 22 males, 34 females Mean age (years): Group 1: 8.3 (range 7 to 9.6), Group 2: 8.1 (range 7 to 9.8) Age range: 7 to 9 years old (mean: 8.2 +/- SD 0.8)
Interventions	Group 1: audiovisual distraction during treatment including delivery of LA Group 2 (control): conventional treatment, including delivery of LA
Outcomes	Anxiety: measured preoperatively and postoperatively using the Facial Image Scale (FIS). Self-reported, 5 faces that best represent patient's emotional state, ranging from 1 to 5 Anxiety and co-operation measured by Modified Venham's clinical ratings of anxiety and co-operative behaviour scale (MVARS). This scale has 6 categories ranging from 0 to 5 Anxiety measuring blood pressure (systolic and diastolic) and pulse rate. Measurements made at: intraoral examination, injection with LA, application of rubber dam, cavity preparation, and tooth restoration
Notes	CONSORT flow chart not presented Declarations of interest: the authors declare no conflicts of interest Sample size calculation made and discussed however, no reference to previous papers or pilot studies for information Consent form and ethical approval obtained Study performed by the same paediatric dentist Pilot study performed with 6 patients that were not included in the study

	Trained, independent assessors. Interexaminers reliability obtained (Cohen's kappa: 0.85)

Risk of bias table

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	High risk	Quote: "The randomization was performed by a dental assistant not participating in the study by assigning the first patient to either group by the toss of a coin, after that the next patient went to the other group" Comment: method described implies that the first patient was assigned randomly, but that every patient after that was assigned via alternation
Allocation concealment (selection bias)	Unclear risk	No discussion regarding allocation concealment is presented
Blinding of participants and personnel (performance bias)	High risk	Children not blinded. No discussion regarding blinding of personnel Quote: "... in the AV-group, before the start of the restorative procedure, the child was introduced to the AV-system (i-theatreTM) and allowed to choose his/her favourite cartoon…"
Blinding of outcome assessment (detection bias)	Unclear risk	No discussion on how blinding of observers was carried out. No discussion whether children in the control group were wearing AV glasses or similar in order to blind raters Quote: "The two observers were blinded, and the tapes were coded during the main study"
Incomplete outcome data (attrition bias)	High risk	Numbers of patients not presented on tables or discussed in text. No CONSORT flow chart therefore no information on number of dropouts and reasons for them
Selective reporting (reporting bias)	Unclear risk	Descriptive statistics on number of patients not presented
Other bias	Low risk	No further bias identified

Al-Namankany 2014

Methods	Study design: randomised controlled trial, parallel design Location: United Kingdom Number of centres: 1

	Setting: hospital Recruitment period: October 2010 to March 2011 Funding source: not reported
Participants	Inclusion criteria: the availability of DVD facilities at home; children aged 6 to 12 years of age; healthy children with American Society of Anaesthesiologists ASA scale, class I and II; and children who were assessed to be dentally anxious based on the score of ≥ 26 on ACDAS Exclusion criteria: children who did not meet the inclusion criteria; children with a learning disability; children who needed emergency dental treatment Number of participants randomised: 68 Number of participants evaluated: 56 Number of males/females: 22 males (Group 1: 11; Group 2: 11); 34 females (Group 1: 16; Group 2: 18) Group 1 mean age (years) = 9.15, median = 9, SD = 2.75 years, 95% CI of the mean: 8.06 to 10.24 years Group 2 mean age (years) = 9.07, median = 9, SD = 2.47 years, 95% CI of the mean: 8.13 to 10.01 years Age range: 6 to 12 years
Interventions	Group 1 (control group): patients were shown a video of a dentist delivering oral hygiene instructions to a 9-year old girl in a non-clinical setting Group 2 (test group): patients were shown a modelling video of the same dentist doing a filling with LA, to the same 9-year old girl, in clinic
Outcomes	ACDAS at baseline, second visit and after video. As ACDAS is not administered following LA, we have not included this in our review VAS: 1: in the waiting area, 2: entering clinic, 3: sitting on dental chair, 4: following dental examination with a mirror, 5: polish or fissure sealant, 6: LA, 7: tooth drilling, 8: extraction. We included parameters 1, 2, 3, and 4 in this review Parents' feedback questionnaire. As this included all treatment and not only delivery of LA, its results were not included in this review
Notes	CONSORT flow chart Declarations of interest: none reported There was a sample size calculation Consent form and ethical approval obtained

Risk of bias table

Bias	Authors' judgement	Support for judgement

Random sequence generation (selection bias)	Low risk	Quote: "The participants were randomly allocated into intervention (modelling video) and control groups with the aid of computer-generated random numbers by the statistician (AP)"
Allocation concealment (selection bias)	Low risk	Quote: ".... were entered into sealed envelopes that were opened in sequence in accordance with patient participation"
Blinding of participants and personnel (performance bias)	Low risk	Quote: "All participating children and the dentists providing dental treatment were blinded to the type of video"
Blinding of outcome assessment (detection bias)	Low risk	Although it was unclear if the investigator was blinded, children and parents report on anxiety and none of the outcomes includes observation of behaviour by an investigator. For this reason we believe there is no detection bias
Incomplete outcome data (attrition bias)	Low risk	Quote: "On the second visit, five children from the modelling group were excluded, three failed to watch the video, two dropped out; and seven children from the control group were excluded (dropped out), but children who failed to watch the video from the control group were not excluded"
Selective reporting (reporting bias)	Low risk	All recorded outcomes were reported on within the results section
Other bias	Low risk	No further bias identified

Allen 2002

Methods	Study design: randomised controlled trial, parallel design Location: United Kingdom Number of centres: 1 Setting: hospital Recruitment period: October 2010 to March 2011 Funding source: not reported
Participants	Inclusion criteria: participants needing restorative treatment with LA, in the maxilla, no discernable limitations of mental status Number of participants randomised: 40 Number of participants evaluated: 40 Number of males/females: Group 1: 70% males, 30% females; Group 2: 85% males, 15% females

	Children with previous experience with LA: Group 1: 65%, Group 2: 70% Age range: 2 to 5 years old Mean age (years): 4.1
Interventions	Group 1 (control): LA with traditional syringe Group 2: LA using the wand LA using the wand was delivered to anterior and middle superior nerve or anterior superior alveolar nerve. LA using traditional syringe was either buccal or palatal
Outcomes	Pain behaviour using 4 categories: body movement, crying, restraints, and stoppage of treatment. The last category was dropped from analysis due to infrequent occurrence. Appointments were video taped. Research assistant rated behaviour in 15-second intervals from the moment the dentist started looking and touching the child, until he stopped
Notes	Consent and ethical approval obtained Same gauge needle used in both groups; topical anaesthetic used for all children Examiner reliability calculated for 15% of the observations

Risk of bias table

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	Quote: "the child was randomly assigned to either the wand or the traditional injection" Method of randomisation has not been reported
Allocation concealment (selection bias)	Unclear risk	Not reported
Blinding of participants and personnel (performance bias)	High risk	Quote: "patients were visually shielded from knowing which local anaesthesia technique he/she received" Comment: unclear if the wand had any sound - typically it does and this may have introduced bias. Operator could not be blinded to the type of LA
Blinding of outcome assessment (detection bias)	High risk	No reference to blinding of observers, however appointments were videotaped and analysis performed from the moment the dentist started touching the child, including crying. Assuming this will imply viewing the

		child's face, the raters would not be blinded to the type of LA used
Incomplete outcome data (attrition bias)	High risk	2 patients were excluded. No reference to which group they belonged, no analysis on their ratings, even though the category they fitted in was described as part of the outcomes Quote: "This behaviour was coded for only two children, one each during the palatal and buccal injections. It was dropped from the analysis due to infrequent occurrence" Not all results could be presented as if the LA delivery was quicker, there were fewer ratings - Quote: "the analyses were limited to 15 second intervals that included at least 35% of the sample in each condition. The palatal injection had insufficient patients remaining after 30 seconds (i.e., three 15 second intervals)"
Selective reporting (reporting bias)	Low risk	All recorded outcomes were reported on within the results section
Other bias	Unclear risk	Delivery of LA with the wand took longer than conventional LA. This may have introduced bias, as it has been reported that time taken to deliver LA influences pain during delivery. Furthermore, as the operator was not blinded to the intervention, it is possible that the difference in delivery times might have been subject to bias. It would possibly have been valuable to standardise the time of delivery of LA in both groups. By the other hand one may argue that slow delivery of LA is one of the advantages of the wand in comparison to conventional LA, as discussed by the authors

Aminabadi 2008

Methods	Study design: randomised controlled trial, parallel design Location: Iran Number of centres: 1 Setting: hospital Recruitment period: unclear Funding source: not reported

Participants	Inclusion criteria: carious lower primary molars requiring inferior alveolar nerve block, no previous experience with intraoral injections, no allergy to lidocaine, no history of pain associated with pulpitis, no relevant medical history, no history of unpleasant experiences in medical settings Number of participants randomised: 78 Number of participants evaluated: 78 Number of males/females: 38 males, 40 females Age range: 4 to 5 years Mean age (years): 4.72
Interventions	Group 1 (control): LA only Group 2: use of counter-stimulation during delivery of LA Group 3: use of counter-stimulation and distraction during delivery of LA
Outcomes	Intraoperative distress measured by the Sound, Eyes and Motor scale (SEM), assessed by 2 dentists (not operator)
Notes	Intraexaminers agreement of 0.87 Declarations of interest: none reported There was no sample size calculation Ethical approval obtained

Risk of bias table

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	Quote: "the patients were coded and a blinded researcher was asked to allocate them into three equal groups by randomised selection of the numbers" Comment: it does not specify how number selection was made
Allocation concealment (selection bias)	Unclear risk	Quote: "blinded researcher" Comment: not discussed how concealment was obtained
Blinding of participants and personnel (performance bias)	High risk	Not discussed, however as interventions were delivered by operator, he/she could not be blinded
Blinding of outcome assessment (detection bias)	High risk	Not reported however, not possible to blind raters to the use of counter-stimulation or not as they needed to see the face in order to assess the SEM scale
Incomplete outcome data (attrition bias)	Low risk	No excluded participants

Selective reporting (reporting bias)	Low risk	All outcomes reported
Other bias	Low risk	No further bias identified

Aminabadi 2009a

Methods	Study design: randomised controlled trial, parallel design Location: Iran Number of centres: 1 Setting: university Recruitment period: 2009 Funding source: not reported
Participants	Inclusion criteria: carious lower primary molars needing inferior alveolar block, no history of post-traumatic stress or dental phobia, no history of unpleasant experiences in medical settings, no previous experience of intraoral injections, no history of pain secondary to pulpitis, no allergy to lidocaine, co-operative patients Number of participants randomised: 160 Number of participants evaluated: 160 Number of males/females: 88 males (Group 1: 45, Group 2: 43); 72 females (Group 1: 35, Group 2: 37) Mean age (years): Group 1: 5.1, Group 2: 5.4 Age range: 5 to 6 years
Interventions	Group 1: no ice pre-cooling prior to topical anaesthetic Group 2: use of ice pre-cooling prior to topical anaesthetic
Outcomes	Intraoperative distress measured by the Sound, Eyes and Motor scale (SEM), assessed by 2 dentists (not operator)
Notes	Treatment delivered by same operator Examiners agreement at 0.88 Declarations of interest: none reported There was no sample size calculation Consent and ethical approval obtained

Risk of bias table

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Quote: "were assigned to one of the two groups by the admitting dentist who drew one card for each patient from a box containing 160 folded cards (80 marked control and 80 marked study)"

Allocation concealment (selection bias)	Unclear risk	Quote: "Concealment of the group assignment was maintained until the statistical analysis was completed" Comment: not discussed how concealment was achieved
Blinding of participants and personnel (performance bias)	High risk	Not discussed, however as interventions were delivered by operator, he/she could not be blinded
Blinding of outcome assessment (detection bias)	Unclear risk	Quote: "A second dentist, blind to the study procedure, assessed patient behavior during injections..." Comment: unclear how the dentist could be blinded to the use of ice but it would have been possible to exclude the rater from the room up to start of LA
Incomplete outcome data (attrition bias)	Low risk	No missing data
Selective reporting (reporting bias)	Low risk	All outcomes reported
Other bias	Low risk	No further bias identified

Asarch 1999

Methods	Study design: randomised controlled trial, parallel design Location: USA Number of centres: 1 Setting: medical centre Recruitment period: not reported Funding source: not reported
Participants	Inclusion criteria: need for restorations under LA; no significant behaviour problems Number of participants randomised: 57 Number of participants evaluated: 57 Age range: 5 to 13 years old
Interventions	Group 1 (control): delivery of LA using a conventional syringe Group 2: delivery of LA using the wand
Outcomes	Perception of pain: measured using a 10-point VAS, colour coded from a narrow white column which widened into wider dark red, corresponding to increasing pain. Pain rating were done after each injection Pain behaviour: measured using 4 categories: non-interfering body movements, crying, movement disruptive to treatment, and movement requiring restraint. This was observed by a research assistant in 15-second intervals. Coding started when dentist looked and touched the mouth and stopped when

	dentist looked away or stopped touching patient. There was a pause for pain rating. As this coding included the restorative treatment and no separate data were given for delivery of LA only, this outcome was not included in this review Treatment satisfaction: measured using a modified version of the abbreviated acceptability rating profile, rated by participants using a 6-point Likert scale. However as there were no separate data for LA and the rating was done following completion of the restorative treatment, this was excluded from our review Amount of time taken for each injection: not included in this Cochrane Review
Notes	Consent and ethical approval obtained Approximately same time taken with the wand and conventional syringe

Risk of bias table

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	Quote: "each subject was then randomly assigned to either the Wand or the traditional syringe condition for administration of local anaesthesia" Comment: method of randomisation not described
Allocation concealment (selection bias)	Unclear risk	Not reported or discussed
Blinding of participants and personnel (performance bias)	High risk	Quote: "the patients were kept blind to which delivery system was used (i.e., patients were visually shielded from seeing the injection device)" Comment: unclear if the wand made any sounds - this may have introduced bias as typically the wand has a sound. Operators could not be blinded to the intervention
Blinding of outcome assessment (detection bias)	Low risk	No discussion whether the observer was blinded to the intervention, however this outcome was not being studied in this Cochrane Review, and for that reason no bias was introduced this way in patient's rating
Incomplete outcome data (attrition bias)	Low risk	No excluded patients

Selective reporting (reporting bias)	Low risk	All recorded outcomes were reported within the results section
Other bias	Unclear risk	Fast injection mode used with the wand - they may have introduced bias as slow mode was not used

Baghlaf 2015

Methods	Study design: randomised single-blind trial, parallel Location: Saudi Arabia Number of centres: not reported Setting: quote: "pediatric dentistry specialty clinics" Recruitment period: November 2012 to April 2013 Funding source: not reported
Participants	Inclusion criteria: age ranging from 5 to 9 years old, physically and mentally healthy, no contraindications for LA, co-operative, as determined by a behavioural rating of 'positive' or 'definitely positive' on the Frankl scale, a diagnosis of a carious primary mandibular second molar requiring pulpotomy Exclusion criteria: medically compromised, unco-operative patients, lack of parental consent Number of participants randomised: 100 Number of participants evaluated: 91: Group 1: 31, Group 2: 30, Group 3: 30 Number of males/females: 39 males, 52 females Age range: 5 to 9 years old
Interventions	Group 1: traditional LA Group 2: computer-controlled LA delivery system (CCLAD) as recommended by the manufacturer - ID Block Group 3: CCLAD with injection in the gingival sulcus, in a 45 degree angle - intraligamental LA
Outcomes	Pain behaviour: assessed in 15-second intervals. 4 pain behaviour codes were scored as present or absent: body movements, crying, restraint, and stoppage of treatment. Occurrences were summed and divided by the total number of intervals assessed to calculate mean pain-related behaviour scores Pain perception: reported following completion of LA using the Wong-Baker Faces Pain Rating Scale
Notes	CONSORT flow chart presented Intraexaminer reliability calculated, with strong agreement Sample size calculation performed but no references or pilot studies discussed for data extraction Use of restraint by the assistant if needed No discussion regarding the level of training of operator or research assistant

Risk of bias table

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	Quote: "The patients were randomly assigned to one of three groups using a block randomisation technique" Comment: technique of randomisation not specified
Allocation concealment (selection bias)	Unclear risk	Discussed that patients were unaware of allocation but no discussion regarding operator/investigator. Quote: "patients were not informed about the group allocation"
Blinding of participants and personnel (performance bias)	High risk	Quote: "The children's eyes were shielded with standard sunglasses, thus they could not distinguish between the anesthetic delivery systems. Because STA produces audible beeps as the injection is administered, and the beeping tones cannot be turned off with a switch, the sounds were produced during all injection methods (STA system or traditional syringe) as an additional measure to ensure that the children were not aware of the method being used" Comment: no discussion whether operator was blinded but operator could not be blinded to the intervention
Blinding of outcome assessment (detection bias)	High risk	Only participants were blinded in this study
Incomplete outcome data (attrition bias)	High risk	No intention-to-treat analysis performed. The authors discussed reasons for exclusion, which included failure of the "anesthesia technique" or extensive bleeding on pulpotomy and 2 more for issues with rubber dam placing
Selective reporting (reporting bias)	Low risk	All recorded outcomes were reported within the results section
Other bias	Low risk	No further bias

Carrasco 2017

Methods	Study design: randomised trial, parallel Location: Mexico

	Number of centres: 1 Setting: clinic at the university Recruitment period: not reported Funding source: not reported
Participants	Inclusion criteria: patients must have never received dental care and had to be seeking attention at the university for the first time and their dental treatment had to include LA Exclusion criteria: not defined Number of participants randomised: 40 Number of participants evaluated: 40 Number of males/females: 16 males, 24 females Age range: 5 to 9 years Mean age (months): 90, SD: 17.15 No reporting of the group age
Interventions	Group 1: hypnosis. Patients had headphones with a record of guided hypnosis playing during appointment Group 2 (control group): patients had headphones with no sound (to block the drill noise with no audio)
Outcomes	Anxiety/pain: assessed with the FLACC scale (Face, Legs, Activity, Cry, Consolability) during LA Heart rate before and during LA Skin conductance before and during LA (excluded from the review)
Notes	Observers were trained and inter-rater reliability obtained Consent and ethical approval obtained Sample size calculation made, however the sample number were small and we are not sure if it can show a difference or not No reference to previous published protocol

Risk of bias table

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	Method of randomisation has not been reported
Allocation concealment (selection bias)	Unclear risk	No discussion regarding allocation concealment
Blinding of participants and personnel (performance bias)	High risk	Blinding of patients was not discussed. However, the authors reported that patients were asked to wear headphone to blind the outcome assessor only. Furthermore, it seems impossible to blind the operator as the headphones for patients in the

		hypnosis group were playing audio during the treatment while patient in the other group had no audio
Blinding of outcome assessment (detection bias)	High risk	Patients in the trail were asked to wear headphones to maintain the FLACC evaluators blind to the group membership. However, children in the experimental group were asked to raise their hand before LA according to the authors and there is no mention if the children in the control group did the same or not
Incomplete outcome data (attrition bias)	Low risk	Only 1 appointment so possibly no dropouts
Selective reporting (reporting bias)	Low risk	All recorded outcomes were reported on within the results section
Other bias	High risk	The authors did not report on patient characteristic and demographics data in the study. Furthermore, the patients in the control group were asked to wear headphones to block drill noise according to the authors which could have introduced bias

Gibson 2000

Methods	Study design: randomised controlled trial, parallel design Location: USA Number of centres: 1 Setting: hospital Recruitment period: not reported Funding source: not reported
Participants	Inclusion criteria: need for restorations in the maxilla under LA; all patients had previous experience of LA; no discernable limitations of mental status Number of participants randomised: 62 Number of participants evaluated: 62 Number of males/females: Group 1: 15 males and 16 females; Group 2: 15 males and 16 females Age range: 5 to 13 years old Mean age (years): Group1: 8.0; Group 2: 8.6
Interventions	Group 1 (control): delivery of LA using a conventional syringe Group 2: delivery of LA using the wand
Outcomes	Pain behaviour: measured by a research assistant in 15-second intervals, using 4 categories: body movement, crying, movements requiring restraint, and movements requiring a temporary halt to

	treatment. Rating of the injection procedure started at the point of tissue penetration but not specified when rating stopped - if after LA or after completion of treatment. However discussed it was "coding of the injection procedure," and for this reason we will accept this was only referring to delivery of LA Perception of pain: rated by each child using a 10-point VAS which included a meter with a red bar moving from 0 to 10. Rated immediately after delivery of LA Overall treatment satisfaction following completion of treatment: included 5 questions and a 6-point VAS ranging from 1 strong disagreement from patient to 6 strong agreement with the statement. Administered at the end of appointment. However, as there were no separate data for LA and the rating was done following completion of the restorative treatment, this was excluded from our Cochrane Review
Notes	Consent and ethical approval obtained

Risk of bias table

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	Quote: "the child was then randomly assigned to either the wand or the traditional syringe" Comment: method of randomisation not reported
Allocation concealment (selection bias)	Unclear risk	Not reported or discussed
Blinding of participants and personnel (performance bias)	High risk	Quote: "the patients were kept blind to which delivery system was used (i.e., patients were visually shielded from seeing the injection device)" Comment: unclear if the wand had any sound - this may have introduced bias. No discussion whether operator was blinded but operator could not be blinded to the intervention
Blinding of outcome assessment (detection bias)	High risk	No information given regarding blinding of observers, however not possible for raters to be blinded to the type of LA used
Incomplete outcome data (attrition bias)	Unclear risk	Quote: "Because injection times varied significantly, statistical analyses were performed only at intervals in which at least 85% of each

		sample were included. Thus, statistical comparisons were only performed on six intervals that were observed" Comment: this means that data could not be collected in all intervals as collection stopped earlier for 1 group
Selective reporting (reporting bias)	Low risk	All recorded outcomes were reported on within the results section
Other bias	Unclear risk	Delivery of LA with the wand took longer than conventional LA. This may have introduced bias, as it has been reported that time taken to deliver LA influences pain during delivery. Furthermore, as the operator was not blinded to the intervention, it is possible that the difference in delivery times might have been subject to bias. It would possibly have been valuable to standardise the time of delivery of LA in both groups. By the other hand one may argue that slow delivery of LA is one of the advantages of the wand in comparison to conventional LA, as discussed by the authors

Huet 2011

Methods	Study design: randomised controlled trial, parallel design Location: France Number of centres: 1 Setting: university hospital Recruitment period: 3 months, not specified when Funding source: not reported
Participants	Inclusion criteria: dental restorative treatments or pulpotomies of primary teeth (canines and molars) requiring dental anaesthesia by buccal infiltration only Number of participants randomised: 30 Number of participants evaluated: 30 Number of males/females: 15 males and 15 females Age range: 7 to 12 years Mean age: not reported
Interventions	Group 1 (control): LA delivered without hypnosis Group 2: hypnosis delivered during treatment, from the moment child is seated on dental chair. A hypnotic trance was considered to have been achieved when the hypnotherapist noted muscular

	relaxation, regular breathing, and immobility (cataleptic state)
Outcomes	Anxiety: using the modified Yale Preoperative Anxiety Scale. This scale includes 22 items grouped into 5 categories (activity, verbal behaviour, expression, alertness, and attitude toward parents), scored from 0 (no anxiety) to 100 (maximum anxiety). Recorded by the assessor and measured at initial interview, on arrival in the waiting room, in the dentist's chair and at the time of the dental anaesthesia LA-related pain and discomfort: assessed using VAS, a self-assessment test from 0 (no pain) to 10 (maximum pain). This was recorded by the child after treatment LA-related pain and discomfort: assessed using the modified Objective Pain Score (mOPS). The mOPS scale includes 5 criteria ranked between 0 and 2 that correspond to behaviour (crying, anxiety, movements) and verbalization of pain. This scale provides a score of 0 (no pain) to 10 (maximum pain). This was recorded by the assessor during LA
Notes	No sample size calculation Treatment delivered by dental students with 2 years experience (5th years) and hypnosis delivered by same trained practitioner Consent and ethical approval obtained

Risk of bias table

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Quote: "randomly assigned by lottery"
Allocation concealment (selection bias)	Unclear risk	Concealment not reported
Blinding of participants and personnel (performance bias)	High risk	Blinding of participants and personnel not discussed, however as hypnosis was delivered during LA, operators and patients could not be blinded
Blinding of outcome assessment (detection bias)	High risk	Blinding of assessor not discussed. Quote: "All anxiety score assessments and interviews with the children were carried out by a single experienced paediatric dentist (AH), who was not involved in the hypnotic, anaesthetic, and dental treatment process." However, the assessor was present at the appointment and for that reason

		not blinded to the intervention - hypnosis/no hypnosis
Incomplete outcome data (attrition bias)	Low risk	Authors report on incomplete data. Quote: "One child excluded because of unusable data," from the intervention group
Selective reporting (reporting bias)	Low risk	The study reported all expected outcomes
Other bias	Low risk	No further bias

Kamath 2013

Methods	Study design: randomised controlled trial, parallel design Location: India Number of centres: 1 Setting: dental clinics - unclear setting Recruitment period: not reported Funding source: not reported
Participants	Inclusion criteria: previous experience of LA, classified as negative behaviour on Frankl scale, prior to treatment Number of participants randomised: 160 Number of participants evaluated: 160 Number of males/females: Group 1: 41 males and 39 females; Group 2: 44 males and 36 females Age range: 4 to 10 years old Mean age (years): Group 1 males: 7.6, SD: 3.4; Group 1 females: 7.2, SD: 3; Group 2 males: 7.8, SD: 3.2; Group 2 females: 7.6, SD: 3.5
Interventions	Group 1 (control): participants told to breathe deeply and count to 10 during delivery of LA Group 2: participants told to breathe deeply and count to 10. Additionally, told to raise the right leg as if they were writing their name in the air continuously and slowly during delivery of LA (WITAUL technique)
Outcomes	Modified Toddler-Preschooler Postoperative Pain Scale for children between 4 and 5 years old (28 in each group). This is comprised of 5 parameters: verbal complaint/cry, groan/moan/grunt, facial expression, restless motor behaviour, and rub/touch painful area. Scores for each parameter ranged from 0 to 10. Recorded by an investigator FACES Pain Scale Revised (FPS - R), for children between 6 and 10 years of age. 6-point scale, with numerical values from 0 to 10. Recorded by the child
Notes	No sample size calculation Consent obtained. Ethical approval not reported

Risk of bias table

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Quote: "The children were randomly assigned to an intervention group or to a control group by flipping a coin"
Allocation concealment (selection bias)	Unclear risk	Not reported or discussed
Blinding of participants and personnel (performance bias)	High risk	Not reported or discussed, however impossible to blind participants and operators to interventions - which involved movement during delivery of LA
Blinding of outcome assessment (detection bias)	High risk	No information given regarding blinding of observers. However, not possible to blind observer
Incomplete outcome data (attrition bias)	Low risk	No participants were excluded - all evaluated and accounted for in results' table
Selective reporting (reporting bias)	Low risk	All recorded outcomes were reported on within the results section
Other bias	Low risk	No further bias identified

Kandiah 2012

Methods	Study design: randomised controlled trial, parallel design Location: United Kingdom Number of centres: 2 Setting: hospital, community service Recruitment period: October 2009 and May 2010 Funding source: not reported
Participants	Inclusion criteria: patients aged 8 to 16 years old, who were graded I according to the American Society of Anesthesiologists (ASA) physical status classification; need for restoration of upper permanent molars with minimal carious lesions (less than 1/3 marginal ridge involved or small occlusal caries) who were asymptomatic and without any associated sinus or pathology Exclusion criteria: patients unable to communicate or with significant needle phobia, patients requiring additional use of conscious sedation; patients with heavily restored dentition or teeth with enamel/dentinal defect. Inability to obtain a positive baseline reading using the electric pulp tester or to obtain positive consent from parents or guardian Number of participants randomised: 30

	Number of participants evaluated: 30 Number of males/females: 11 males (Group 1: 7, Group 2: 4); 19 females (Group 1: 8, Group 2: 11) Age range: 8 to 16 years Median age: 12 (SD: 2.177)
Interventions	Group 1 (control): LA delivered with a conventional syringe Group 2: LA delivered using the wand
Outcomes	Onset of LA: evaluated and compared using a pulp tester - this outcome was not in the inclusion criteria of this Cochrane Review and for this reason was not included Pain experience. The authors provided separate data for this outcome in their paper. A modified VAS scale was used for children to rate their experience - a 100 mm scale with descriptive anchors at each end. Distance on the scale was turned into a percentage number, which was then transformed into categories of no pain (< 20%), mild (20% to 40%), moderate (40% to 60%), severe (60% to 80%), and intolerable pain (> 80%)
Notes	There was a sample size calculation Consent and ethical approval obtained Patient information leaflet and VAS scale and altered following patients' feedback Time taken to deliver LA: in the descriptive statistics.This was not one of the study's outcome measures and was not correlated to pain or distress

Risk of bias table

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Quote: "The statistician carried out the randomisation by block allocation, based on a random table of numbers, according to a computer programme of random allocation (http://randomisation.com)"
Allocation concealment (selection bias)	Low risk	Quotes: "The randomisation data was sent to the specialist in paediatric dentistry in Barnsley CDS (RM) while the investigator remained blind. The random allocations were placed into envelopes by RM who then held the envelopes that were only given to the investigator when the patient arrived for treatment" and "The envelope would only be opened by the

		investigator immediately before the LA"
Blinding of participants and personnel (performance bias)	High risk	Quote: "In this study, although the patient was blind to the LA given, the single operator could not be blinded for the practical purposes of LA delivery and in order to measure the outcomes" Comment: blindness of the operator during delivery, even though not feasible, might have added bias The patients were blinded to the intervention: the same dialogue was used and "The wand's bleeping system was an indicator of LA delivery. To avoid this being a potential source of bias, it was planned that the beeping sound would be used for both groups of patients"
Blinding of outcome assessment (detection bias)	Low risk	The operator did not rate the behaviour of the child and for that reason we believe there was no bias introduced to the outcome included in this Cochrane Review as we believe the child was truly blinded to the intervention
Incomplete outcome data (attrition bias)	Low risk	Quote: "Three cases were abandoned due to problems associated with the electric pulp tester (EPT). Out of the three, one patient started crying when the EPT was used and for the others the EPT response was unreliable. The parents of one patient did not consent for their child to take part in the study" Comment: all patients accounted for
Selective reporting (reporting bias)	Low risk	All recorded outcomes were reported on within the results section
Other bias	Low risk	No further bias identified

Lee 2013

Methods	Study design: randomised controlled trial, parallel design Location: Korea Number of centres: 1 Setting: university hospital Recruitment period: unclear Funding source: not reported

Participants	Inclusion criteria: need for a mandibular block; no behavioural management problems; no gender, race, or ethnic restrictions Exclusion criteria: emergency cases were not selected Number of participants randomised: 134 Number of participants evaluated: 134 Number of males/females: 77 males (Group 1: 35, Group 2: 42); 57 females (Group 1: 19, Group 2: 38) Age range: Group 1: 4 to 12 years, Group 2: 3 to 12 years
Interventions	Group 1 (control): conventional delivery of LA Group 2: pulling of mucosa over tip of needle at insertion of LA syringe
Outcomes	Treatments videotaped and assessed using the Sound, Eyes, and Motor (SEM) scale. Results of SEM divided into 2 categories: comfort and discomfort. Discomfort was divided into 3 subscales: mild, moderate, and severe pain. Results reported separately for boys and girls; maxillary and mandibular LA
Notes	The same dentist delivered LA 2 dental students assessed children, intra and interexaminer agreements established at 90% No sample size calculation Consent and ethical approval obtained

Risk of bias table

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	Quote: "randomly divided into the following 2 groups: alternative and conventional" Comment: not discussed how sequence generation was performed
Allocation concealment (selection bias)	Unclear risk	Allocation concealment not reported
Blinding of participants and personnel (performance bias)	High risk	Quote: "this study design was not double blind, i.e., the dentist was aware of the procedure" Comment: it would not be possible for the operator to be blinded to the intervention, but this might have been a source of bias; no reference to blinding of participants
Blinding of outcome assessment (detection bias)	High risk	No reference to blinding of assessors. Quote: "Data recorded in the

		videotape were rated using the Sounds, Eyes, and Motor (SEM) scale by 2 independent evaluators (trained dental students)" Comment: not possible to blind raters to intervention
Incomplete outcome data (attrition bias)	High risk	Quote: "Children were excluded if technical problems occurred during the videotaping procedures", however this was not further discussed. No descriptors of how many children were excluded for this reason. Attrition in each group is unclear
Selective reporting (reporting bias)	Low risk	The study reported all expected outcomes
Other bias	Low risk	No further bias identified

Mittal 2015

Methods	Study design: randomised controlled trial, with parallel arms Location: India Number of centres: 1 Setting: university hospital Recruitment period: not reported Funding source: not reported
Participants	Inclusion criteria: healthy physically and mentally, co-operative (Frankl positive or definitive positive), children needing extraction of upper molars Exclusion criteria: conscious sedation, children receiving treatment that could modify their behaviour or awareness of pain Number of participants randomised: 100 Number of participants evaluated: 100 Number of males/females: 54 males and 46 females Age: 9.14 years average Age range: 8 to 12 years of age indicated in methods; 8 to 13 years old indicated in results
Interventions	Group 1: LA delivered with the wand (single tooth anaesthesia system) Group 2 (control): conventional LA delivered
Outcomes	VAS immediately after LA Objective evaluation using the Sound, Eyes and Motor pain reactions (SEM) scale, ranging from 1 to 4. Measured by operator and an independent investigator who was present in the surgery Physiological assessment: heart rate measured with a pulse oxymeter. Readings were average of readings taken on 3 occasions: 8 minutes prior to LA: readings every 2 minutes; during buccal infiltration:

	readings every 15 seconds; and during palatal infiltration: readings every 15 seconds
Notes	CONSORT flow chart not presented Declarations of interest: not reported Sample size calculation: not reported Consent form and ethical approval obtained observer in the surgery LA delivered by the same paediatric dentist Standardised amounts of LA solution delivered buccally and palatally for every patient Interexaminers reliability for SEM measurement: 0.7; calibration undertaken with 15 patients

Risk of bias table

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Quote: "random sampling using Chi^2 method"
Allocation concealment (selection bias)	Unclear risk	No discussion regarding allocation concealment is presented
Blinding of participants and personnel (performance bias)	Unclear risk	Not discussed
Blinding of outcome assessment (detection bias)	Unclear risk	No discussion on blinding of observers, however observer was present during appointment
Incomplete outcome data (attrition bias)	Low risk	No reference to dropouts. Patients were randomised just before treatment, only 1 appointment, therefore possibly no dropouts. No CONSORT table given
Selective reporting (reporting bias)	Low risk	All outcomes were reported
Other bias	High risk	Time taken to deliver LA not recorded or not standardised. This may have included bias as some authors studying the same intervention report on time taken and others standardise this factor

Nieuwenhuizen 2013

Methods	Study design: randomised controlled trial, parallel design Location: Netherlands Number of centres: 3 Setting: 3 paediatric practices but unclear which setting Recruitment period: over the period of 4 months, year not specified Funding source: not reported

Participants	Inclusion criteria: need routine restorative dental treatment under LA, children not on special education Number of participants randomised: 118 children Number of participants evaluated: 112 children Number of males/females: 59 males and 59 females Age range: 4 to 6 years Mean age: 66 months, SD: 9 months (mean age Group 1: 65.3; mean age Group 2: 66.5)
Interventions	Group 1 (control): LA delivered with the wand Group 2: LA delivered using Sleeper One
Outcomes	Children were video taped and assessed by 2 independent observers Pain-related behaviour: using a modified Wong-Baker Faces scale - fixed protocol every 15 seconds. Looking at body movement, muscle tension, crying and screaming, verbal protest and bodily resistance. The frequency of the behaviour was divided by the total number of intervals scored Distress: measured using a Venham (modified) clinical rating of anxiety and co-operative behaviour. This was rated from 0 (relaxed) to 5 (out of contact/untreatable). The highest score in the appointment was used Self-reported pain: using a faces pain scale-revised Dental anxiety: using the Dental Subscale of the Children's Fear Survey Schedule (CFF-DS). This was completed by the parents and a threshold of 32 was used to determine low (below 32) and high anxiety (over 32). Not clear when the parents completed this. Preoperative anxiety only (without comparison to a postoperative measurement of anxiety) is not an outcome for this review, as unsure of when this was undertaken, it was not included
Notes	No sample size calculation 2 independent observers had a interexaminers agreement with a Cohen's kappa of 0.94 Consent and ethical approval obtained

Risk of bias table

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Quote: "each child was assigned to the use of either the WAND or Sleeper One based on a randomisation list generated by SPSS (SPSS, 17,0: Chicago, IL, USA)

Allocation concealment (selection bias)	Unclear risk	Not reported
Blinding of participants and personnel (performance bias)	High risk	It was not discussed if the patient was blinded to treatment. Not reported whether operators were blinded, but it would be impossible to blind operators to the intervention as 2 different devices were used
Blinding of outcome assessment (detection bias)	High risk	Quote: "The observers were aware of the type of CCLAD used"
Incomplete outcome data (attrition bias)	High risk	5 children were excluded due to difficulties with video and 1 was a child with special needs. No description of which group these children were included in
Selective reporting (reporting bias)	Low risk	All recorded outcomes were reported on within the results section
Other bias	High risk	6 children were found to have high bone density and for that reason it was not possible to deliver intraosseous LA. Intraligamental anaesthetic was delivered, however there is no description as to which group were these children included. This may have introduced bias into the results

Nuvvula 2015

Methods	Study design: randomised controlled trial, parallel design Location: India Number of centres: 1 Setting: hospital Recruitment period: April to October 2012 Funding source: not reported
Participants	Inclusion criteria: between 7 to 10 years, no previous dental experience, no relevant medical history, with a score of C12 on faces version of Modified Child Dental Anxiety Scale (MCDAS(f)), categorised by Wright's modification of Frankl behaviour rating scale, requiring LA inferior alveolar block for pulp therapies in lower primary molars Number of participants randomised: 90 Number of participants evaluated: 90 Number of males/females: 49 males (Group 1: 16, Group 2: 17, Group 3: 16); 41 females (Group 1: 14, Group 2: 13, Group 3: 14) Mean age (years): 8.4; Group 1: 8.67, SD = 1.6 years; Group 2: 8.4, SD = 1.1 years; Group 3: 8.23, SD = 1.1 years

	Age range: 7 to 10 years
Interventions	Group 1 (control group): LA with routine behaviour management Group 2: LA with MP3 player in addition to behaviour management Group 3: LA with 3D audiovisual glasses in addition to behaviour management
Outcomes	MCDAS(f) scores General behaviour on Frankl and Houpt scales Physiological parameters: pulse rate Child's interview
Notes	CONSORT flow chart Declarations of interest: none reported There was a sample size calculation Consent form and ethical approval obtained

Risk of bias table

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Quote: "To identify the order of intervention in each treatment group, restricted randomisation or block randomisation (permuted block randomisation) was used in the study with random block sizes of 4 and 6. A table of random numbers was used to generate the random allocation sequence"
Allocation concealment (selection bias)	Low risk	Quote: "Centralised or third party assignment was used as an allocation concealment mechanism to prevent selection bias, and it was an open trial"
Blinding of participants and personnel (performance bias)	High risk	Quote: "was an open trial" Comment: patients and operators not blinded
Blinding of outcome assessment (detection bias)	High risk	Quote: "was an open trial" Comment: unsure if it would have been possible to blind the investigators
Incomplete outcome data (attrition bias)	Low risk	No withdrawals reported
Selective reporting (reporting bias)	Low risk	Results cover all outcome measures
Other bias	Low risk	No further bias identified

Oberoi 2016

Methods	Study design: randomised controlled study Location: India

	Number of centres: not reported Setting: not reported Recruitment period: not reported Funding source: not reported
Participants	Inclusion criteria: child needing a pulp therapy in primary or permanent mandibular molars, no previous dental experience and were ASA I Exclusion criteria: not reported Number of participants randomised: 200 Number of participants evaluated: 200 Number of males/females: 94 males (Group 1: 48, Group 2: 46); 106 females (Group 1: 52, Group 2: 54) Age range: 6 to 16 years
Interventions	Group 1: hypnotic induction to administer LA Group 2: LA without hypnotic induction
Outcomes	Physical and verbal resistance: resistance to delivery of LA, such as high hand movements, leg movements, crying or verbal protests and/or orophysical resistance. Assessed by independent observer blinded to intervention Pulse rate: measured at baseline, at tissue penetration and on administration of LA Change in oxygenation level: from baseline until LA delivery
Notes	Declarations of interest: not reported No sample size calculation Ethical approval and consent obtained

Risk of bias table

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Quote: "The method of allocation consisted of creating 200 slips of equal size and shape, 100 marked with I and 100 marked with II. The slips were folded and pooled in a bowl and shuffled. Each child was asked to pick a slip from the bowl"
Allocation concealment (selection bias)	Unclear risk	Not discussed whether the slips and the bowl were opaque and if the children and investigators could see allocation. Quote: "The slips were folded and pooled in a bowl and shuffled. Each child was asked to pick a slip from the bowl"

Blinding of participants and personnel (performance bias)	High risk	Not discussed but would not be possible to blind either
Blinding of outcome assessment (detection bias)	Low risk	Quotes: "A second observer, blinded to whether the child had received hypnosis, was called into the operatory by pressing a button that gave a signal in the adjoining room" and "independent statistician who was blinded to the group assignment"
Incomplete outcome data (attrition bias)	Low risk	No excluded participants
Selective reporting (reporting bias)	Low risk	All recorded outcomes were reported within the results section
Other bias	High risk	Wide age range, with no division into groups for analysis. No discussion of ages of patients in each group, although authors calculated a statistically significant correlation between age and resistance in the experimental group (Group 1)

Paryab 2014

Methods	Study design: randomised controlled trial, parallel design Location: Iran Number of centres:1 Setting: university Recruitment period: 2010 Funding source: not reported
Participants	Inclusion criteria: 1 carious lesion needing pulpotomy, on a lower primary molar, no previous hospitalizations or dental visits, no relevant medical history Number of participants randomised: 46 Number of participants evaluated: 46 (23 children on each group) Number of males/females: 22 males and 24 females Age range: 4 to 6 years (SD: 2 months)
Interventions	Group 1 (control): first visit: tell-show-do, prophylaxis and fluoride therapy in the dental chair. Reward given at the end of the appointment; second visit (1 week later): LA and pulpotomy Group 2 (film modelling): first visit: video of tell-show-do and fluoride therapy only (not chairside). Reward given following video; second visit (1 week later): LA and pulpotomy
Outcomes	Anxiety and co-operation scored using Venham Scale and Frankl index. Venham Scale scores from 0

	(co-operative) to 5 (unco-operative) behaviour. Frankl index is a 4 index scale from definitely negative to definitely positive. Children were video taped and assessed by 2 independent observers at the time of injection and at the beginning of tooth preparation. However, only the final results (means) are given for these assessments. No separate data for LA given, therefore these outcomes were eliminated from our analysis, as not included in our inclusion criteria Heart rate prior to and after LA: separate date for LA therefore we only analysed this outcome Parents filled in a questionnaire on demographics (excluded from this review)
Notes	There was no sample size calculation Consent and ethical approval obtained CONSORT flow chart

Risk of bias table

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	Quote: "the child was enrolled in one of the study groups based on balanced block randomisation" Comment: no discussion how this process was done
Allocation concealment (selection bias)	Unclear risk	Not reported
Blinding of participants and personnel (performance bias)	High risk	Not reported. It would be possible for the operator to be blinded on the second appointment - when delivering treatment. As not discussed by authors, it is possible that bias might have been introduced by this
Blinding of outcome assessment (detection bias)	Low risk	Quote: "independently evaluated by 2 paediatric dentists who were blind to the grouping of the children"
Incomplete outcome data (attrition bias)	Low risk	Quote: "A child in the first group was excluded from the study because of his definitely negative behavior (Score I in Frankl index)" Comment: authors describe reason for exclusion
Selective reporting (reporting bias)	Low risk	All recorded outcomes were reported on within the results section
Other bias	Low risk	No further bias identified

Sridhar 2019

Methods	Study design: randomised controlled trial, parallel design Location: India Number of centres: 1 Setting: hospital Recruitment period: 8 months between June 2017 and January 2018 Funding source: not reported
Participants	Inclusion criteria: age group of 7 to 11 years, in good systemic health, requiring dental treatment under maxillary buccal infiltration Exclusion criteria: children exhibiting definitely negative behaviour (Frankl's behaviour rating 1) during the dental examination, presenting with acute pain and requiring emergency dental treatment, or suffering from any illness requiring special medical care Participants assessed for eligibility: 78 Number of participants randomised: 66 (Group 1: 33, Group 2: 33) Number of males/females: 40 males, 26 females Mean age (years): 8.57 (SD 1.07) Age range: 7 to 11 years old
Interventions	Visit 1: dental examination, inclusion, and acclimatization visit Visit 2: treatment visit Group 1: relaxation training exercise in the form of "bubble breath exercise" taught Group 2: routine verbal reinforcement while giving infiltration anaesthesia (control)
Outcomes	Pulse rate: recorded 5 minutes before the start of the injection, during the injection and 5 minutes after the injection Scoring of behaviour on video by 2 observers using Frankl scale: 4-point scale from 1 to 4 Self-reported pain: Wong-Baker Faces scale immediately after LA: 6-point scale from no hurt to hurts the most Faces Legs Activity Cry and Consolability (FLACC) scale (to a maximum score of 10), divided into mild (1 to 3), moderate (4 to 6), and severe (7 to 10)
Notes	Consent and ethical approval obtained Standardisation of the technique of the LA administration by the operator (same gauge needle and topical anaesthetic used for all children) Examiner reliability calculated for 15% of the observations

	Intraexaminer and interexaminer reliability, assessed using Cohen's kappa statistic, revealed a kappa value of 1 and 0.82, respectively

Risk of bias table

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Quote: "Block randomisation method with a block size of four was used. The block sequences (ABAB, BABA, AABB etc) were generated following which the statistician performed random allocation of the samples to the blocks using a random number table"
Allocation concealment (selection bias)	Low risk	Quote: "the treatment group codes so generated (A or B) were entered into cards and placed in envelopes that were sequentially numbered. The envelopes were rendered opaque by covering the cards with aluminium foil and then sealed"
Blinding of participants and personnel (performance bias)	High risk	Quote: "blinding of patients, ... was not possible due to the nature of intervention"
Blinding of outcome assessment (detection bias)	High risk	Quote: "blinding .. the examiners who scored the pain reaction and behaviour was not possible due to the nature of intervention.."
Incomplete outcome data (attrition bias)	Low risk	No dropouts
Selective reporting (reporting bias)	Low risk	All recorded outcomes were reported within the results section
Other bias	High risk	The breathing exercise, 1 visit before the injection was introduced for children before the treatment, could have introduced bias for children in the intervention group and as a result affect the reporting of pain scores at the end of treatment

Tahmassebi 2009

Methods	Study design: randomised controlled trial, parallel design Location: United Kingdom Number of centres: 1 Setting: hospital Recruitment period: not reported

	Funding source: not reported
Participants	Inclusion criteria: children aged between 3 and 10 years inclusive, no previous dental experience, in need of at least 1 maxillary restoration LA, mentally capable of communicating, satisfying the criteria of group I of the ASA guidelines as issued by the American Association of Anesthesiologists (1963) and who understood English Exclusion criteria: medically and mentally compromised children, children with previous dental experience, children with a history of significant behaviour management problems, children referred specifically because of needle-phobia and where consent from parent or guardian was not possible Number of participants randomised: 38 Number of participants evaluated: 38 (Group 1: 18, Group 2: 20) Number of males/females: 16 males and 22 females (Group 1: 10 males and 8 females; Group 2: 6 males and 14 females) Age range: 39 to 120 months Mean age: 81.9 months; SD ± 23.2 months
Interventions	Group 1 (control): delivery of maxillary LA using a conventional syringe (buccal, intrapapillary and palatal infiltrations) Group 2: delivery of maxillary LA using the wand (buccal and direct infiltrations delivered)
Outcomes	Anxiety: rated by the participants using a Venham's scale Pain perception: rated by children after delivery of LA, using a modified VAS after LA Child's pain experience: rated for each child by operator using a standard VAS Parents rated chid's pain: using a standard VAS
Notes	There was a sample size calculation Ethical approval and consent were obtained Same operator, standardised speech during delivery of LA Children with no experience of LA Participants not matched for gender

Risk of bias table

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	Quote: "The supervisor (JT) controlled the randomisation" but no discussion of the process of randomisation used

Allocation concealment (selection bias)	Low risk	Quote: "the operator (MN) was blind to the block size, and was given a list of envelopes to provide the injection to patients. Each envelope was opened immediately before the LA"
Blinding of participants and personnel (performance bias)	High risk	Quote: "The subjects were not 'blinded' to the method of LA used" Comment: although it would have been difficult for the participants to be blinded, this may have introduced bias to the study. Not reported if operator was blinded but would not have been possible to do so
Blinding of outcome assessment (detection bias)	High risk	As the operator rated each participant using a modified VAS, this may have introduced additional bias, as he was not blinded to the intervention
Incomplete outcome data (attrition bias)	Low risk	No excluded participants
Selective reporting (reporting bias)	Low risk	All recorded outcomes were reported on within the results section
Other bias	Low risk	No further bias identified

Tung 2018

Methods	Study design: randomised trial, parallel Location: authors affiliated to USA. No discussion where study was conducted Number of centres: 1 Setting: not discussed Recruitment period: not discussed
Participants	Inclusion criteria: age group between 7 to 14 years old; in good health, taking no medications, who needed 1 operative dental appointment requiring a maxillary infiltration injection or mandibular inferior alveolar block and long buccal injection, and exhibited a Frankl 3 or 4 behaviour rating score at the past dental examination Exclusion criteria: systemic medical conditions and developmental delay Number of participants randomised: 150 Number of participants evaluated: 150 Number of males/ females: 81 girls, 69 boys Mean age (years): Group 1: 11.1, Group 2: 10.7, Group 3: 11.1 with 50 participants in each group
Interventions	Group 1: the operator's thumb was placed adjacent to the injection site and the forefinger was placed extraorally to ensure that equally slight pressure and vibration were applied from opposing directions. A

	traditional aspirating syringe was used to deliver LA. Manual vibration was applied for approximately 1 to 2 mm, with a frequency of vibrations of 1 to 2 cycles per second. After 5 seconds of manual vibration, the needle was inserted into the soft tissue and LA was delivered Group 2: the DentalVibe® was used, per the manufacturer's recommendations. The vibrating tip was placed on the oral mucosa at the injection site and allowed to vibrate for 10 seconds prior to needle placement at close proximity to 1 of the vibrating prongs. Vibration was allowed to continue 2 seconds following withdrawal of the needle Group 3: a traditional aspirating syringe was used to deliver LA. No manual vibration was applied
Outcomes	Self-reported pain: using Wong-Baker Faces scale that extends from 0 (no pain) to 10 (worst pain) Objective assessment was observed by assessing the patients' pulse rate using a pulse oximeter at 4 different intervals: when seated in the dental chair, during application of topical anaesthetic, during the needle penetration/duration of the injection, and immediately after the injection
Notes	Declarations of interest: not reported Sample size calculation performed and discussed Ethical approval obtained 2 calibrated investigators: calibration method described satisfactory. No discussion of level of training of the operators Other data collected: patient demographics and baseline clinical variables Height and weight taken and not understood why 2 sites of injection (maxillary and mandibular), however, they were equally distributed between groups Time of placing LA can vary in time and there was no discussion if they controlled duration of delivery of LA

Risk of bias table

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Quote: "A random number sequence was generated, using the Stata (Stata Corp, College Station, Texas, USA) command uniform to assign treatment sequence order to subjects at enrolment"

Allocation concealment (selection bias)	Unclear risk	No discussion regarding allocation concealment is presented
Blinding of participants and personnel (performance bias)	High risk	Blinding of patients and operator was not discussed. However, it is not possible due to the nature of intervention
Blinding of outcome assessment (detection bias)	Low risk	Self-reported and objective measures. Therefore no detection bias
Incomplete outcome data (attrition bias)	Low risk	Authors reported that due to the very short duration of their study, there was no potential for loss to follow-up, so all the recruited participants remained in the study for analysis, precluding the possibility of selection bias
Selective reporting (reporting bias)	Low risk	All outcomes reported
Other bias	Low risk	No other bias

Ujaoney 2013

Methods	Study design: randomised controlled trial, parallel design Location: India Number of centres: 1 Setting: university hospital Recruitment period: October 2005 to the end of April 2006 Funding source: not reported
Participants	Inclusion criteria: children < 15 years of age; no history of dental injections; currently being treated for 1 of the following conditions: over-retained teeth, badly carious teeth failed root canal therapies; and dental procedures that required the use of LA; no relevant medical history Exclusion criteria: mentally challenged children and children with medical problems that negated the use of LA Number of participants randomised: 143 (40 did not consent to the procedure and 3 were lost to follow-up) Number of participants evaluated: 100 Number of males: 49 (Group 1: 23, Group 2: 26) Mean age (years): Group 1: 8.46, SD: 2.01; Group 2: 8.73, SD: 2.39 Age range: not reported
Interventions	Group 1 (control): LA delivered with conventional syringe Group 2: LA delivered with camouflage syringe - each study subject in this arm was given a choice to

	select the favourite shape and colour of the camouflage syringe
Outcomes	Venham's clinical rating (VCR) scale used to score participants by 2 assessors. This measures behavioural and physiological parameters on a scale from 0 to 5 with a score of 0 corresponding to a relaxed, smiling child and a score of 5 corresponding to a screaming child actively involved in escape behaviour. Unclear when assessment was made and frequency of assessments and for this reason not used for this review Scales for Movement, Crying and Overall Behaviour, by Venham in 1977, scored by 2 assessors: Movement (score range 1 to 4), Crying (score range 1 to 4), and Overall Behaviour (score range 1 to 6) After the treatment the child (or a parent in case of a very young child) was requested to fill out the Venham's picture test (VPT) questionnaire. The child (or parent) had to choose from a faces panel the one that best matched the child's feelings before and during the administration of the anaesthetic. Scores ranged from 0 to 8 Parents were asked to fill the parental emotional stress questionnaire (PESQ) which enquires about expectations from the dentist(s), child's tendency to cry in the dental clinic, and the parents' emotional status. Unclear when assessment was made, possibly prior to treatment, but not discussed. Not included in our review Parents filled in a recall questionnaire at a follow-up visit, enquiring about children's dental behaviour and attitude after the treatment, whether the child experienced any psychological trauma due to the dental experience, and the child's emotion after the day's treatment. Not included in our review
Notes	There was a sample size calculation 2 trained assessors, interexaminers agreement reported, high agreement Consent and ethical approval obtained

Risk of bias table

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	Quote: "100 children were recruited and divided using block randomisation (block sizes 2, 4 and 6) into two equal sized groups of 50 children each"

		Comment: no discussion of how they were randomised
Allocation concealment (selection bias)	Unclear risk	Allocation concealment was not reported or discussed
Blinding of participants and personnel (performance bias)	High risk	Quote: "This concurrent parallel, two-arm, non-blinded randomised controlled trial" Comment: not possible to blind operator due to the different presentations of the syringes. Additionally, children chose the look of the syringe - intervention included viewing of the syringe, therefore blinding would not have been possible or desirable
Blinding of outcome assessment (detection bias)	High risk	Assessors not blinded to intervention, as intervention syringes looked different to conventional syringes, however this may have introduced bias Quote: "This concurrent parallel, two-arm, non-blinded randomised controlled trial"
Incomplete outcome data (attrition bias)	High risk	3 participants were lost to follow-up, rejected and not included in the analysis as they could not complete the recall questionnaire Quote: "three were rejected at the stage of analysis since they were lost to follow-up and so the recall questionnaire could not be completed." Although the authors discussed that quote: "We did not anticipate attrition issues as the primary outcome assessment was to be done within one hour of the intervention," they do not discuss to which arm did these 3 participants belong and for that reason it is not possible to determine the effect of possible attrition bias for both primary and secondary outcomes
Selective reporting (reporting bias)	Low risk	All outcomes reported
Other bias	Low risk	No other bias

Versloot 2005

Methods	Study design: randomised controlled trial, parallel design Location: Netherlands

	Number of centres: 1 Setting: "specialist clinic" - unclear which setting Recruitment period: period of 4 months, year not reported Funding source: not reported
Participants	Inclusion criteria: need for treatment with LA; between 4 and 11 years; fluent in Dutch; and no suspected or known developmental delay Number of participants randomised: 130 Number of participants evaluated: 125 Number of males/females: 68 males (Group 1: 27, Group 2: 41); 57 females (Group 1: 31, Group 2: 26) Age range: 4 to 11 years (Group 1: 4 to 10.5, Group 2: 4 to 11) Mean age (years): 6.2, SD: 1.6 (Group 1: 6.0, Group 2: 6.7) No differences found between groups regarding age, gender, experience of LA in the previous 6 months
Interventions	Group 1 (control): LA delivered using a conventional syringe Group 2: LA delivered using the wand Sites for wand injections were: anterior middle superior alveolar (9 patients); palatal anterior superior alveolar (28 patients); and for lower teeth periodontal ligament LA was used (25 patients) Conventional LA following topical anaesthetic. Sites for conventional injections were: in the maxillary teeth, buccal (27 patients) and palatal (5 patients); and for lower teeth, mandibular block was used (25 patients)
Outcomes	Children were video taped and all treatments were analysed by 2 independent observers: a psychologist and a third year dental student. Observations were divided into 3 stages: anticipation phase (from the moment child enters surgery to start of LA), during delivery of LA, and after delivery of LA Pain-related behaviour: rated in 15-second intervals. 5 behaviours were assessed: body movement muscle tension, crying or screaming, verbal protest, and bodily resistance. This was measured prior to and during delivery of LA Distress: measured using Venham's (modified) clinical rating of anxiety and co-operative behaviour. The scale consists of 6 points: relaxed, uneasy, tense, reluctant, resistant, out of contact or untreatable, from 1 to 6. This was measured prior to and during delivery of LA Self-reported pain: measured using a modified version of VAS, with 11 points from 0 (no pain) to

	10 (worst pain possible). 6 faces, expressing different levels of pain/distress, were added for children to choose the face matching their own level of pain/distress. This was completed by children following delivery of LA Dental anxiety: parents completed the parent version of the Dental Subscale of the Children's Fear Survey Schedule (CFSS-DS). Each item is scored on a 5-point scale, from 1 to 5. Scores below 32 are considered to be of non-anxious children. This questionnaire was filled in by parents as the treatment was being carried out - parents were kept in waiting room while child was being treated. Preoperative anxiety only (without comparison to a postoperative measurement of anxiety) is not an outcome for this review, as unsure of when this was undertaken, it was not included in this review
Notes	There was a sample size calculation Consent and ethical approval obtained Topical anaesthetic used for conventional LA but not for the wand Use of validated scales Interexaminers agreement found to be 0.87 for the Venham's scale and 0.93 for pain-related behaviour

Risk of bias table

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Quote: "Each child was randomly assigned to either the Wand or the traditional injection condition, based on a randomisation list generated by SPSS"
Allocation concealment (selection bias)	Unclear risk	Unsure how concealment was achieved, however reference to dentists not knowing what type of LA was to be delivered until they decided which tooth to treat. Quote: "To avoid possible preference of the dentists, they were required to decide on the tooth to be treated before the anaesthetic condition was told"
Blinding of participants and personnel (performance bias)	High risk	Not possible to blind operators to the intervention. However, this may have introduced bias, as this may have influenced the speed of LA delivery, which was found to be different in both groups - see 'other bias' section

		Not discussed if children were blinded to intervention, however it is discussed that same explanation was given to children prior to the operators knowing what LA was to be used. Typically the wand has a 'beeping noise' however this was not addressed in the discussion
Blinding of outcome assessment (detection bias)	High risk	Not reported whether observers were blinded to the intervention. Although it might not be possible to blind the observers due to the different presentation of both syringes, it may have introduced bias in rating the children's behaviour
Incomplete outcome data (attrition bias)	Unclear risk	Quote: "Five children had to be excluded afterwards: two because they were too old; one because of technical difficulties with the video recorder; and two because the dentist did not adhere to the randomisation protocol." Some data cannot be given due to early discontinuation of assessment: 10 children were excluded from the last interval of the second phase of analysis (during delivery of LA), as they were in the control group and delivery of LA ended before the second analysis was completed.
Selective reporting (reporting bias)	Low risk	All recorded outcomes were reported on within the results section
Other bias	Unclear risk	LA in the control group was delivered significantly quicker than in the study group Quote: "The Wand injection was found to take an average of 152.5 s (SD: 40.6), whereas the traditional injection took an average of 33.9 s (SD: 20.0)." This may have introduced bias, as it has been reported that time taken to deliver LA influences pain during delivery. It would possibly have been valuable to standardise the time of delivery of in both groups. Furthermore, as the operator was not blinded to the intervention, it is possible that the difference in delivery times might have been biased. By the other hand one may say that slow

		delivery of LA is one of the advantages of the wand in comparison to conventional LA, as discussed by the authors, and by standardising delivery times, bias could also have been introduced Topical anaesthetic used for conventional LA but not for the wand - this might have influenced pain experience and the child's experience might have been different in children who had topical anaesthetic prior to LA

Versloot 2008

Methods	Study design: randomised controlled trial, parallel design Location: Netherlands Number of centres: 1 Setting: specialised dental care clinic Recruitment period: not reported Funding source: not reported
Participants	Inclusion criteria: need for 2 subsequent treatment sessions with LA, age between 4 and 11 years and no suspected or known developmental delay Number of participants randomised: 147 (Group 1: 76, Group 2: 71) Number of participants evaluated: 127 (Group 1: 67, Group 2: 60) Number of males/females: 76 males and 71 females Age range: 4 to 11 years Mean age (years): 6.4, SD: 1.7 (Group 1: 6.3, SD: 1.7; Group 2: 6.4, SD: 1.6) No differences found between groups regarding age, gender, experience of LA in the previous 6 months
Interventions	Group 1 (control): LA delivered using a conventional syringe for 2 consecutive appointments Group 2: LA delivered using the wand for 2 consecutive appointments Sites for wand injections were: anterior middle superior alveolar; palatal anterior superior alveolar and for lower teeth periodontal ligament LA was used Sites for conventional injections were: for the maxilla, buccal and palatal; and for lower teeth, mandibular block was used. Topical anaesthetic used in both groups
Outcomes	Children were video taped and all treatments were analysed by 2 independent observers: a psychologist

	and a third year dental student. Observations were divided into 3 stages: anticipation phase (from the moment child enters surgery to start of LA), during delivery of LA, and after delivery of LA Pain-related behaviour: rated in 15-second intervals. 5 behaviours were assessed: body movement muscle tension, crying or screaming, verbal protest and bodily resistance. This was measured prior to and during delivery of LA Distress: measured using Venham's (modified) clinical rating of anxiety and co-operative behaviour. The scale consists of 6 points: relaxed, uneasy, tense, reluctant, resistant, out of contact or untreatable, from 1 to 6. This was measured prior to and during delivery of LA Self-reported pain: measured using a modified version of VAS, with11 points from 0 (no pain) to 10 (worst pain possible). 6 faces, expressing different levels of pain/distress, were added for children to choose the face matching their own level of pain/distress. This was completed by children following delivery of LA Dental anxiety: parents completed the parent version of the Dental Subscale of the Children's Fear Survey Schedule (CFSS-DS). Each item is scored on a 5-point scale, from 1 to 5. Scores below 32 are considered to be of non-anxious children. This questionnaire was filled in by parents as the treatment was being carried out - parents were kept in waiting room while child was being treated. Preoperative anxiety only (without comparison to a postoperative measurement of anxiety) is not an outcome for this review, as unsure of when this was undertaken, it was not included in this review
Notes	Consent and ethical approval obtained Observers were trained and there is a reliability analysis The video tapes from the study were evaluated by both observers independently and in case of disagreement a final rating was reached by joint decision

Risk of bias table

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Quote: "Each child was randomly assigned to either the Wand (n = 71) or the traditional injection (n = 76) condition based on a randomisation

		list generated by SPSS (SPSS Inc, 12.0, Chicago, USA)"
Allocation concealment (selection bias)	Unclear risk	Unsure how concealment was achieved, however reference to dentists not knowing what type of LA was to be delivered until they decided which tooth to treat. Quote: "To avoid possible preference of two dentists, they were required to decide on the tooth to be treated before the anaesthetic condition was revealed"
Blinding of participants and personnel (performance bias)	High risk	Not possible to blind operators to the intervention. However, this may have introduced bias, as this may have influenced the speed of LA delivery, which was found to be different in both groups - see 'other bias' section Not discussed if children were blinded to intervention. Typically, the wand has a 'beeping noise' however, this was not addressed in the discussion
Blinding of outcome assessment (detection bias)	High risk	Not reported whether observers were blinded to the intervention. Although it would not be possible to blind the observers due to the different presentation of both syringes, it may have introduced bias in rating the children's behaviour
Incomplete outcome data (attrition bias)	Unclear risk	Quote: "For 20 children only their first treatment session could be included due to rescheduling of the second appointment." CONSORT flow chart shows that 9 were in the control group and 11 in the intervention group
Selective reporting (reporting bias)	Low risk	All recorded outcomes were reported on within the results section
Other bias	Unclear risk	Different speeds for delivery of LA in control and study groups may have biased results, due to reports of increased speed causing more pain. Furthermore, as the operator was not blinded to the intervention, it is possible that the difference in delivery times might have been biased. By the other hand slow delivery is one of the benefits of the wand, additionally authors report that: "children who are already reacting negatively to an

		injection seem to be longer in distress with the Wand system", and this may have introduced bias too

Footnotes

ACDAS = Abeer Children Dental Anxiety Scale; ASA = American Society of Anesthesiologists physical status classification system; AV = audiovisual; CI = confidence interval; IANB = inferior alveolar nerve block; LA = local anaesthetic; SD = standard deviation; VAS = visual analogue scale.

Characteristics of excluded studies

Aghahi 2017

Reason for exclusion	Adult sample

Alamoudi 2016

Reason for exclusion	Comparison of different types of anaesthesia

Aminabadi 2009b

Reason for exclusion	RCT comparing different sites of LA - however, different LA techniques were used, which is not within the remit of this review

Ashkenazi 2005

Reason for exclusion	Delivery of intrasulcular LA - 3 groups each using different behaviour management techniques, including sedation which was not used in all groups

Ashkenazi 2006

Reason for exclusion	Comparison of different techniques for injection of LA (not the remit of this review), using a computerised system

Babaji 2017

Reason for exclusion	No LA administered

Baghdadi 2000

Reason for exclusion	Comparison of different types of anaesthesia

Bajric 2015

Reason for exclusion	Not an RCT

Brignardello-Petersen 2018

Reason for exclusion	Opinion paper

Brownbill 1987

Reason for exclusion	Randomised study comparing 2 different interventions on different gauge needles with no control group

Chan 2012

Reason for exclusion	Evaluation of pulsed Nd:YAG laser for inducing pulpal analgesia

Eren 2013

Reason for exclusion	No LA administered

Fathi 2012

Reason for exclusion	RCT to study the effect of distraction and counter-stimulation, however results discuss only type/technique of LA. No results for intervention and therefore does not fit our inclusion criteria

Filcheck 2005

Reason for exclusion	RCT on audiovisual distraction as intervention for children's restorative treatment. No separate data for delivery of LA

Gazal 2016

Reason for exclusion	Adult sample

Hembrecht 2013

Reason for exclusion	Partially cross-over, no separate data for outcome investigated using a parallel design

Hermes 2005

Reason for exclusion	Includes patients over 18 years old, no separate data for children

Hoge 2012

Reason for exclusion	RCT on the use of video eyewear as intervention, however no separate data for delivery of LA, hence not fitting our inclusion criteria

Houpt 1997

Reason for exclusion	RCT on topical anaesthetics, study included participants over the age of 18 years

Klein 2005

Reason for exclusion	RCT measuring the quality of 2 different techniques of LA and 2 different delivery systems. Quality of LA assessed. Although disruptive behaviour during LA was assessed we felt this study could not be included as it compared 2 different techniques of LA (i.e.: palatal approach anterior superior nerve block and multiple supraperiosteal injections)

Koyuturk 2009

Reason for exclusion	RCT comparing efficacy of LA delivery by 2 dentists, both using the wand and conventional LA. In results and discussion study also compares children's behaviour during delivery of LA using wand or conventional syringe between practitioners and within the same practitioner. Study included children requiring maxillary and mandibular LA but unclear how many children were in each group. Unclear if children received both LAs, and if not, not

	discussed whether children were seen again for completion of treatment

Kuscu 2006

Reason for exclusion	Assessment of the physical appearance of dental injectors

Lodaya 2010

Reason for exclusion	Study measures transcutaneous electrical nerve stimulation as a type of anaesthetic. It measures effectiveness, therefore does not fit our inclusion criteria

Marwah 2005

Reason for exclusion	RCT on music intervention. No separate data for each treatment or for delivery of LA

Melamed 1976

Reason for exclusion	RCT looking at the effect of film modelling in reducing disruptive behaviour in children. No separate data for delivery of LA

Naidu 2004

Reason for exclusion	Study investigates different techniques of LA, which is not the remit of this review

Nayak 2006

Reason for exclusion	Study comparing 3 different LA agents

NCT01883232

Reason for exclusion	Assessment of the efficacy of analgesic buffering with sodium bicarbonate

NCT03680625

Reason for exclusion	Medical setting, not dental

Oulis 1996

Reason for exclusion	Study comparing mandibular infiltration versus mandibular block anaesthesia

Pedersen 2017

Reason for exclusion	Adult sample

Peretz 1999

Reason for exclusion	RCT studying the effect of breathing as a distraction technique during delivery of LA. Study excluded as nitrous oxide was used in some but not all subjects

Prabhakar 2007

Reason for exclusion	No separate data for delivery of LA

Ram 2006

Reason for exclusion	RCT comparing 2 different LA techniques delivered using the Wand (palatal approach anterior superior alveolar injection and periodontal ligament injection)

	and supraperiosteal infiltration using a conventional syringe

Ram 2010

Reason for exclusion	Comparison of behaviour in children using nitrous oxide on one group and using audiovisual glasses on another group. Not RCT

Ram 2012

Reason for exclusion	Different techniques of LA measured over 2 visits, not the remit of this review

Roeber 2011

Reason for exclusion	RCT on the effect of vibrajet. Nitrous oxide sedation used on about half the patients in control and intervention groups. Excluded as per protocol as nitrous oxide not used equally in control and test groups

Roghani 1999

Reason for exclusion	Study evaluating the efficacy of different LA

Sammons 2007

Reason for exclusion	Treatment performed under general anaesthetic and measures effectiveness

Shahi 2018

Reason for exclusion	Adult sample

Sharma 2014

Reason for exclusion	Study evaluating efficacy of different forms of topical anaesthesia

Sixou 2008

Reason for exclusion	It measures effectiveness, not RCT, no control group

Sixou 2009

Reason for exclusion	No control group, not RCT

Stecker 2002

Reason for exclusion	LA not delivered to participants

Vika 2009

Reason for exclusion	Behavioural interventions to increase acceptance of LA in phobic patients over 5 appointments. Intervention in adults

Wahl 2001

Reason for exclusion	Comparison of different anaesthetic solutions, not in our inclusion criteria

Wambier 2018

Reason for exclusion	No LA given (study is for rubber dam clamp placement)

Wilson 1999

Reason for exclusion	No separate data for intraoperative distress during provision of LA

Wright 1991

Reason for exclusion	Not true RCT as sequence determined by a non-random method

Footnotes
LA = local anaesthetic; RCT = randomised controlled trial.

Characteristics of studies awaiting classification

Xia 2012

Methods	Study design: randomised controlled trial, parallel design Location: China Number of centres: 1 Setting: hospital Recruitment period: not reported in the abstract Funding source: not reported in the abstract
Participants	Inclusion criteria: not reported in the abstract Number of participants randomised: 235 Age range: 2 to 8 years old
Interventions	Group 1 (control): guardians received a pamphlet on how to clean children's teeth, prior to treatment Group 2: guardians received a pamphlet about how to help a child to co-operate with the dentist during dental treatment
Outcomes	Children's heart rate was recorded at different time points: before the treatment, at LA, during the treatment, and at the end of the treatment Modified Venham's clinical anxiety scale Co-operative behaviour rating scale Corah Dental Anxiety Scale for parents
Notes	Study in Chinese - only abstract available in English, to be translated

Footnotes

LA = local anaesthetic.

Characteristics of ongoing studies

NCT02084433

Study name	Comparison of intraosseous anaesthesia using a computerized system (QuickSleeper) to conventional anaesthesia (QUICK)

Methods	Study design: randomised controlled trial, parallel design (and split-mouth design) Location: France
Participants	Inclusion criteria: for split-mouth design: patients with at least 2 first permanent molars requiring the same treatment with anaesthesia; for parallel-arm design: patients with first permanent molar requiring treatment with anaesthesia; vital pulp; patient did not take any pain medication 48 hours before randomisation; non-opposition of the child and 2 holders of parental participation in the study; treatments can be conservative treatment or endodontic treatment limited to pulpotomy Exclusion criteria: patients with periodontal disease (periodontal pockets or tooth mobility) or radiological defects (necrosis, furcation or periapical radiolucency); disabled or autistic patients; patients with cancer, heart disease or sickle cell anaemia Estimated number of participants to be enrolled: 160 Elligible age range: 7 to 15 years old
Interventions	Group 1 (control): conventional LA Group 2: intraosseous LA
Outcomes	Pain reported by the patient according to VAS at the end of the injection/infiltration Latency (in minutes) evaluated by examining the sensitivity of the sulcus using a probe (an exam will be conducted every minute until the sulcus is insensitive to the probe) Need for additional anaesthesia during the treatment using VAS Pain felt during the treatment using VAS
Starting date	January 2015
Contact information	Frédéric Courson (frederic.courson@parisdescartes.fr) Violaine Smaïl-Faugeron (violaine.smail-faugeron@parisdescartes.fr)
Notes	

NCT02578160

Study name	Effectiveness of tell-show-do behaviour-management technique during LA in preschool children
Methods	Study design: randomised controlled trial, parallel design Location: Brazil
Participants	Inclusion criteria: preschool children with severe dental caries who need dental pulp treatment or tooth extraction of inferior primary molars or both

	Exclusion criteria: preschool children with history of allergies to lidocaine (LA); with systemic or neurological diseases; who have received local dental anaesthesia before this study Estimated number of participants to be enrolled: 52 Elligible age range: 36 to 71 months old
Interventions	Group 1 (control): conventional delivery of LA Group 2: tell-show-do for delivery of LA
Outcomes	Preschool children's anxiety level: Facial Image Scale (FIS) Preschool children's pain levels: Wong-Baker Faces Pain Scale, at the end of LA Preschool children's behaviour: Frankl behavioural rating scale at baseline and during LA Heart rates Parent's anxiety levels: Corah's dental anxiety scale (DAS) - parent questionnaire
Starting date	October 2015
Contact information	Evelyn Alvarez Vidigal (evevidigal@usp.br) Jenny Abanto (jennyaa@usp.br)
Notes	

NCT02591797

Study name	Effectiviness of hand/eyes/mouth behaviour management technique during LA in preschool children
Methods	Study design: randomised controlled trial, parallel design Location: Spain
Participants	Inclusion criteria: preschool children with severe dental caries who need dental pulp treatment or tooth extraction of inferior primary molars or both Exclusion criteria: preschool children with history of allergies to lidocaine (LA); with systemic or neurological diseases; who have received local dental anaesthesia before this study; who do not understand Spanish or Valencian language Estimated number of participants to be enrolled: 52 Elligible age range: 36 to 71 months old
Interventions	Group 1 (control): conventional technique Group 2: hand-eye-mouth technique - distraction technique using a sequence of movements in a fun way
Outcomes	Preschool children's anxiety levels: Facial Image Scale (FIS) Preschool children's pain levels: Wong-Baker Faces Pain Scale

	Preschool children's behaviour: Frankl behavioural rating scale at baseline and during LA procedure Heart rates: at baseline and during LA
Starting date	October 2015
Contact information	Ana María Leyda Menendez (odualey@yahoo.es) Marta Ribelles Llop (marta.ribelles@uch.ceu.es)
Notes	

NCT03566212

Study name	Efficacy of camouflaged syringe versus conventional syringe (ECC)
Methods	Study design: randomised controlled trial, parallel design Location: India
Participants	Inclusion criteria: retained teeth, badly carious teeth, mobile teeth, requiring a dental procedure under LA Exclusion criteria: mentally challenged children, those with medical conditions contraindicating the use of LA or surgical procedures or both Estimated number of participants to be enrolled: 60 Elligible age range: 3 to 12 years old
Interventions	Group 1: conventional syringe; LA was administered in first group using conventional syringe Group 2: camouflage syringe; LA was administered in second group using camouflage syringe
Outcomes	Anxiety levels: Chotta Bheem and Chutki scale Behaviour rating: Frankl behaviour rating scale
Starting date	August 2017
Contact information	Sneha D Suwarnkar, Saraswati Dhanwantari Dental College and Hospital, Parbhani, India
Notes	

NCT03902158

Study name	Use of virtual reality glasses during anaesthesia in behaviour, anxiety and pain perception of children
Methods	Study design: randomised trial, parallel design Country: Brazil
Participants	Inclusion criteria: good general health, no prior dental experience involving anaesthesia in the last 2 years, need for restorative treatment or exodontia under LA Exclusion criteria: physical or mental disabilities, report of poor behaviour during dental treatment Estimated number of participants to be enrolled: 44 Elligible age range: 5 to 9 years old

Interventions	Group 1: virtual reality glasses Group 2 (control): distraction techniques. No glasses will be used
Outcomes	Perception of pain: using VAS scale
Starting date	April 2019
Contact information	Marília L Goettems (mariliagoettems@hotmail.com)
Notes	

NCT03917121

Study name	Pain control of needle-free versus needle injected LA for pulpotomy of upper primary molars in children
Methods	Study design: randomised trial, parallel design Country: Egypt
Participants	Inclusion criteria: apparently healthy (classified as American Society of Anesthesiologists (ASA) I); vital deeply carious maxillary first primary molars indicated for pulpotomy; no previous dental experience; co-operative behaviour (rating 3 or 4 on Frankl category rating scale) Exclusion criteria: refuse to give assent to participate or have parents/caregivers refusing to sign the informed consent form Estimated number of participants to be enrolled: 46 Elligible age range: 6 to 8 years
Interventions	Group 1: jet anaesthesia Group 2 (control): conventional infiltration anaesthesia
Outcomes	Pain during pulpotomy: score on Faces Pain Scale-Revised and score on Sound, Eyes, and Motor (SEM) scale Pain during injection: score on Faces Pain Scale-Revised and score on Sound, Eyes, and Motor (SEM) scale Need for additional anaesthesia: recorded as a binary (yes/no) outcome
Starting date	August 2019
Contact information	Lobna S Mohamed (lobna_mohamed@dentistry.cu.edu.eg) Mariam M Aly (mariam.mohsen@dentistry.cu.edu.eg)
Notes	

NCT03953001

Study name	Effect of a vibration system on pain reduction during injection of local dental anaesthesia in children

Methods	Study design: randomised, parallel, single blinded Location: Saudi Arabia
Participants	Inclusion criteria: children 5 to 12 years of age, positive or definitely positive behaviour on Frankl scale 6, children receiving treatment on the dental chair, free from allergies to topical anaesthetic used in the study, parental consent for child participation in the study Exclusion criteria: those in need of treatment under general anaesthesia, children with allergies from topical anaesthesia Estimated number of participants to be enrolled: 51 Elligible age range: 5 to 12 years
Interventions	Group 1: BuzzyBuzz external distractor Group 2 (control): conventional maxillary anaesthetic infiltration
Outcomes	Self-reported pain intensity: VAS of pain intensity Parents' perception for the child tolerance of pain: observational pain rating scale External observation for facial and physical expression: using Sound, Eyes, and Motor (SEM) scale Faces Legs Activity Cry Consolability (FLACC) scale: range 0 to 10
Starting date	January 2018
Contact information	Jehan AlHumaid, Imam Abdulrahman Bin Faisal University, College of Dentistry, Dammam, Saudi Arabia
Notes	

Footnotes
LA = local anaesthetic; VAS = visual analogue scale.

Additional tables

Table 10: Outcome measures of included studies

Pain/anxiety scale or measurement	Description	Recorded by	Study
Abeer Children Dental Anxiety Scale (ACDAS)	19 item, cognitive Likert scale	Self-reported	Al-Namankany 2014
Visual Analogue Scale (including modified versions)	Self-reporting of pain based on a line ranging from no pain to worst pain.	Self-reported; investigator; parents/guardians	Al-Namankany 2014 Asarch 1999 Gibson 2000 Huet 2011 Kandiah 2012 Mittal 2015 Tahmassebi 2009 Versloot 2005 Versloot 2008
Parents feedback questionnaires	varied	Parents/guardians	Al-Namankany 2014
4-category scale of distress	4-point scale measuring: body movement, crying, restraints and stoppage of treatment	Investigator	Allen 2002
Sound, eye and motor (SEM) scale		Investigator	Abdelmoniem 2016 Aminabadi 2008, Aminabadi 2009b Lee 2013 Mittal 2015
4-category scale of distress	4-point scale measuring: non-interfering body movements, crying,	Investigator	Asarch 1999

	movement disruptive to treatment, movement requiring restraint		
4-category scale of distress	body movement, crying, movements requiring restraint, movements requiring a temporary halt to treatment.	Investigator	Baghlaf 2015 Gibson 2000
Modified Yale preoperative anxiety scale	22 item grouped into 5 categories. Ranging from 0 to 10.	Investigator	Huet 2011
Modified objective pain score	5 criteria ranging from 0 to 2, with an overall maximum score of 10	Investigator	Huet 2011
Modified Toddler-Preschooler Postoperative Pain Scale	5 parameters. Scores ranging from 0 to 10	Investigator	Kamath 2013
FACES Pain Scale Revised	6-face scale ranging from 0 to 10	Self-reported	Kamath 2013 Nieuwenhuizen 2013
Wong-Baker faces scale	6-face scale for pain behaviour raging from no hurt to hurts worst	Self-reported	Abdelmoniem 2016 Baghlaf 2015 Nieuwenhuizen 2013
Modified Venham scale	6-point scale ranging from 0 (relaxed) to 5 (out of contact or untreatable)	Investigator	Nieuwenhuizen 2013 Versloot 2005 Versloot 2008 Al-Khotani 2016
Venham scale	6- point scale ranging from 0 (cooperative) to 5 (uncooperative	Investigator	Paryab 2014 Tahmassebi 2009 Ujaoney 2013

Dental sub scale of the children's fear survey schedule (CFF-DS)	15 items with a 5-point scale per item. Ranging from 1 (not afraid at all) to 5 (very afraid)	Self-reported	Nieuwenhuizen 2013 Versloot 2005 Versloot 2008
Modified Child Dental Anxiety Scale: faces: MCDAS(f)	6 questions scale, with the total score ranging from 5 (little or no anxiety) to 30 (extreme anxiety)	Self-reported	Nuvvula 2015
Frankl scale	4-point scale from definitely negative to definitely positive.	Investigator	Paryab 2014
Scales for Movement, Crying and Overall Behaviour	Movement (score range 1-4), Crying (score range 1-4), and Overall Behavior (score range 1-6)	Investigator	Ujaoney 2013
Venham's picture test (VPT) questionnaire	9-point face scale ranging from 0 to 8.	Investigator; self-reported	Ujaoney 2013
Parental emotional stress questionnaire (PESQ)	45-point questionnaire with each statement ranging from 1 (strongly disagree) to 5 (strongly agree)	Parents/guardians	Ujaoney 2013
Recall questionnaires		Parents/guardians	Ujaoney 2013
5-category scale of distress	5-point scale measuring body movement muscle tension, crying or screaming, verbal protest and bodily resistance	Investigator	Versloot 2005 Versloot 2008
Facial Image scale (FIS)	5-point scale with faces that best represent the child's emotional state	self-reported	Al-Khotani 2016
Physical resistance to delivery of LA	High hand movements, leg movements, crying or verbal protests and/or oro-physical resistance	Investigator	Oberoi 2016
Heart rate	continuous values	objective measurement	Al-Khotani 2016 Mittal 2015 Oberoi 2016
Blood pressure	continuous values	objective measurement	Al-Khotani 2016

Oxygenation	continuous values	objective measurement	Oberoi 2016

Table 11 : Comparison 1: audiovisual (music versus audiovisual glasses versus control; audioviual glasses versus control)

Study	Outcome	Intervention 1(t1): music distraction	Intervention 2(t2): audiovisual distraction	Control	Results
Nuvula 2015	Anxiety (MCDAS(f)	before LA: 21.5 (2.4 sd; 95 % CI 20.6–22.4)	before LA: 22.2 (4.0 sd; 95 % CI 20.7–23.7)	before LA: 20.6 (2.4 sd; 95 % CI 19.7–21.5)	1. t1(before vs after LA): p=0.001 t2 (before vs after LA): p=0.001 Control (before vs after LA): p=0.83. 2. Intergroup comparison: t1 vs control: before LA p= 0.7; After LA p= 0.001 t2 versus control: before LA p=0.14 after LA p=0.001 t1 versus tt2: before LA p=1.0; after LA p=0.001
		after LA: 14.1 (4.4 sd; 95 % CI 12.4–15.7)	after LA: 8.3 (2.5 sd; 95 % CI 7.3–9.2)	after LA: 20.9 (7.2 sd; 95 % CI 18.2–23.5)	
	Pulse rates	before treatment: 89.3 (3.3 sd; 95 % CI 88.1–90.6)	before treatment: 104.6 (2.9sd; 95 % CI 103.5–105.6)	before treatment: 95.4 (5.6 sd;95 % CI 93.3–97.5)	p value before treatment versus during LA (t 1; t2 and control)= 0.001 Intergroup comparison: t1 vs control: before treatment p= 0.01; During LA p= 0.001 t2 versus control: before treatment
		during LA: 102.4 (8.1sd; 95 % CI 99.4–105.5)	during LA: 109.4 (5.0 sd; 95 % CI 107.5–111.2)	during LA: 119.0 (13.1 sd; 95 % CI 114.1–123.9)	

					p= 0.01; During LA p= 0.001 t1 versus t2: before treatment and during LA p=0.001
	Behaviour (Frankl scale)	1. before vs during LA(p value): treatment1=0.002; treatment 2= 0.001; control=0.01. 2. Intergroup comparison(p value): t1versus control (before treatment)=0.42 (after treatment)=0.02; t2 versus control (before treatment)=0.01 (after treatment)=<0.001; t1 versus t2 (before treatment)=0.07 (after treatment)=0.01			
	Behaviour (Houpt scale)	Intergroup comparison during LA(p value): t1versus control =0.31; t2 versus control=0.003; t1 versus t2 =0.009			
Study	**Outcome**	**Treatment with audiovisual distraction (group 1)**		**Control (group 2)**	**Results**
Al-Khotani 2016	Anxiety (Facial Image scale - FIS)		Authors stated" there were no significant differences in mean (SD) FIS scores between the AV-group; 1.93 (1.15) and CTR-group (1.68 ± 0.86) (p = 0.570)."Mean values for the whole procedure given (including restorative treatment). However no individual values for LA, given other than a graphs. For this reason not possible to include this outcome. Email sent to author requesting separate values rather than whole treatment means.		
	Anxiety (Modified Venham's clinical ratings of anxiety and cooperative behaviour scale - MVARS)		The authors stated"When the cooperative behaviour was analyzed (MVARS), there was a significant difference between groups with lower mean (SD) MVARS scores in the AV-group (0.14 ± 0.36) compared to the CTR-group (0.75 ± 0.52) (p = 0.03)." Mean values for the whole procedure given (including restorative treatment). However no individual values for LA, given other than a graphs. For this reason not possible to include this outcome. Email sent to author requesting separate values rather than whole treatment means.		

	Pulse rate		**Before LA: Mean:** 95.9 (SD= 10.3) **After LA** Mean: 98.6 (SD= 12.2)	**Before LA: Mean:** 94.3 (SD=14.4) **After LA** Mean: 99.4 (SD=14.5)	Significant increase of PR during LA, in the control group (group2) p=0.04. Increase not significant in the study group (group 1) p=0.27
	Blood pressure		**Before LA:** Systolic blood pressure 111.7 (SD=10.7) Diastolic blood pressure 65.2 (SD=7.5) **After LA** Systolic blood pressure 115 (SD=6.3) Diastolic blood pressure 66.8 (SD=6.3)	**Before LA:** Systolic blood pressure 112 (SD=10) Diastolic blood pressure 67.8 (SD=9) **After LA** Systolic blood pressure 110.9 (SD=9.6) Diastolic blood pressure 64.5 (SD=5.8)	There is actually a decrease in systolic BP in the control group but the authors say: "Although s-BP seemed to be higher during injections with local anaesthesia in both groups". no comparative statistics for before and after LA only
Study	**Outcome**	**intervention 1:** **audiovisual distraction (VR Box)**	**intervention 2:** **audiovisual distraction (tablet)**	**Control group 3**	
Al-Halabi 2018	**Behavioral assessment** The 'Face, Legs, Activity, Cry, Consolability' scale (FLACC scale	The authors provided data as comparison between groups with no individual data that can be used for any further analysis. The authors stated that no significant difference was noticed between three groups (p = 0.454). We have attempt to contact the main author but no clarification was received.			

	Pain assessment The Wong-Baker FACES pain rating scale	The authors stated that no significant difference was noticed between three groups in pain assessment (p = 0.536). We are not able
	Pulse rate from when the patients seated to immediately after IAN block .	The authors stated that "Then one-way Anova statistical test was done, significant difference was noticed between three groups in the heart pulse rate scale (P=0.0430)" No other information was provided

Table 12: Comparison 2: Pre-cooling versus conventional treatment

Study	Outcome	Treatment	Control	Results
Aminabadi 2009a	Distress: (SEM scale; 0-4 for each of 4 categories), intra-operatively, investigator	sound:1.15 eye: 1.50 movement: 1.76 sum: 4.41 (n=80)	sound:2.54 eye: 3.25 movement: 2.78 sum: 8.57 (n=80)	within groups: p>0.05”; between groups: p<0.05 (Anova)

Table 13: Comparison 3: The wand versus conventional LA

Study	Outcome	Intervention	Control	Results
Allen 2002	Pain behaviour (4-category scale of distress), 15 intervals, from the moment the dentist started looking and touching the child, until he stopped (overall pain behaviour)	disruptive behaviour: 50%	disruptive behaviour: 71%	t=2.10 p<0.5 fisher’s exact
		crying: 30%	crying: 57%	t=2.4 p<0.5 fisher’s exact
		body movement: 28%	body movement: 49%	t=2.43 p<0.5 fisher’s exact
		Restraint: 3%	Restraint: 34%	t=3.44 p<0.1 fisher’s exact
	Pain behaviour (4-category	disruptive behaviour: 25%	disruptive behaviour: Palatal: 80% Buccal: 75%	“the mean number of 15 second

	scale of distress), 15 intervals, from the moment the dentist started looking and touching the child, until he stopped (initial 15 seconds)			intervals with restraints was significantly fewer during the entire Wand injection (mean=0.30+/-0.73) than during the two traditional injections (1.15+/-1.69), t(25.9)=2.06, p<0.5" fisher's exact test
		crying: 15%	crying: Palatal:70% Buccal: 55%	
		body movement: 15%	body movement: Palatal:60% Buccal: 40%	
		Restraint:0%	Restraint: Palatal:45% Buccal: 20%	
Study	**Outcome**	**Intervention**	**Control**	**Results**
Asarch 1999	Pain perception (VAS; 10-point-scale), immediately after LA, participant rating	Block: 5.00 Buccal: 4.38 Palatal:3.80	Block: 4.062 Buccal: 3.35 Palatal: 3.93	no further information

Study	**Outcome**	**Group 1 – traditional LA(ID Block)**	**Group 2 – CCLAD IDBlock**	**Group 3 – CCLAD Intraligamental**	**Results**
Baghlaf 2015	Pain behaviour (4-point scale), 15 second intervals	Mean: 0.8165 (SD=0.766, n=31)	Mean: 0.4513 (SD=0.6, n=30)	Mean: 0.0890 (SD=0.105, n=30)	ANOVA p<0.5 group 3 statistically significantly lower (p<0.01)
	Pain perception (Wong-aker FACES Pain Rating Scale) following LA	Mean: 1.39 (SD=0.2, n=31)	Mean: 0.87 (SD=0.133, n=30)	Mean: 0.13 (SD=0.063, n=30)	post-hoc test, p<0.5 between groups 1 and 2: p=0.044 between groups 2 and 3: p=0.003 between groups1 and 3: p<0.001

Study	**Outcome**	**Intervention**	**Control**	**Results**
Gibson 2000	Pain behaviour (4-	disruptive behaviour (%):	disruptive behaviour(%): 42%	"significantly fewer patients

	category scale of distress), 15 intervals, from puncture. Unclear when it stopped but discussed it is "coding if injection procedure"	Palatal: 77% Buccal: 45%		cried or exhibited body movements during the first interval of the wand injection than patients given the traditional palatal injection (Chi squared+6.62, 11.78, respectively p<0.5)".
		crying(%): Palatal:74% Buccal: 32%	crying(%): 42%	
		body movement(%): Palatal:39% Buccal: 19%	body movement(%): 3%	
		Restraint (n): Palatal:5 Buccal: 1%	Restraint(n): 1 1%	
	Pain perception (VAS; 10-point-scale), immediately after LA, participant rating	Palatal:4.9 Buccal: 2.7	3.4	Less patients scored high pain ratings in the wand compared to palatal injection (Chi squared=3.32, p<0.10)
Study	**Outcome**	**Intervention**	**Control**	**Results**
Kandiah 2012	Pain (Modified VAS 0-100%); after LA. Percentages were divided into three categories: no pain (<20%), mild (20 - 40%), moderate (40-60%), severe (60-80%), intolerable pain (>80%).	No pain: 14/13 Mild: 0/15 Moderate: 1/15	No pain: 12/13 Mild: 1/15 Moderate: 2/15	"The treatment group had marginally more patients (14/15) expressing that no pain at all was experienced as opposed to the control group (12/14)."
	Time taken to deliver LA (minutes)	Median: 2.200 (1.53 to 4.21 IQR) N=15	Median:2.120 (1.39 to 3.40 IQR) N=15	"The findings from this study suggest that the median for both groups

				was approximately the same"
Study	**Outcome**	**Intervention**	**Control**	**Results**
Mittal 2015	Self-reported anxiety: Visual Analog Scale (VAS) immediately after LA.	Buccal infiltration: Mean VAS: 1.24 (SD=0.74) Palatal infiltration: Mean VAS: 2.94 (SD=1.35)	Buccal infiltration: Mean VAS: 1.16 (SD=0.96) Palatal infiltration: Mean VAS: 2.38(SD=1.23)	Buccal infiltration treatment vs control p=0.64 palatal injection treatment vs control p-0.03 (t test)
	Observed anxiety: using the sound, eye and motor pain reactions (SEM scale), ranging from 1 to 4. Measured by operator and an independent investigator who was present in the surgery.	Buccal infiltration: Mean SEM: 1.64 (SD=1.14) Palatal infiltration: Mean SEM: 3.16 (SD=1.28)	Buccal infiltration: Mean SEM: 1.08 (SD=0.94) Palatal infiltration: Mean SEM: 2.44 (SD=1.31)	buccal infiltration treatment vs control p=0.01 palatal injection tretament vs control p= 0.01 (t test)
	Physiological assessment: Heart rate measured with a pulse oximeter. Readings were average of readings taken on three occasions: a) 8 minutes prior to LA: readings every 2 minutes b) during buccal	Before injection. Mean HR: 83.52 (SD=5.10) During Buccal infiltration (Mean HR): 99.3 (SD=7.90) During palatal injection (Mean HR): 102.26 (SD=7.61)	Before injection Mean HR: 83.64 (SD=4.54) During injection Mean HR: 102.46 (SD=9.38)	uccal infiltration tretament vs control p=0.36 palatal injection treatment vs control p=0.91 (t test)

	infiltration: readings every 15 seconds c) during palatal infiltration: readings every 15 seconds.			
Study	**Outcome**	**Intervention**	**Control**	**Result**
Tahmassebi 2009	1. Participant reported Anxiety (Modified Venham Scale, 1-8), prior to and after LA.	No separate descriptives for conventional LA/the Wand. Difference of anxiety between the two groups given on a graph.	No separate descriptives for conventional LA/the Wand. Difference of anxiety between the two groups given on a graph.	Mean (anxiety difference): -2 (1.96 sd), n=18 p=0.976 (95% CI); two-sample t-test . "There was no significant difference in anxiety change between the two groups at 5% level with P value of 0.976"
	2. Participant reported Pain (Modified VAS, 0-100%), after LA. Percentages were divided them into three categories: no pain (<20%), mild (20 - 40%), moderate (40-60%), severe (60-80%), intolerable pain (>80%).	no pain 50% mild 15% moderate 5% severe/ intolerable 15%	no pain 45% mild 10% moderate 35% severe/ intolerable 5%	"no significant difference in pain sensation between the two groups at 5% level (P=0.710)." two-sample t-test.
	2. Operator reported Pain	mild pain: 20% intolerable	mild pain: 40% intolerable	

	(VAS, 0-100%), after LA. Percentages were divided them into three categories: no pain (<20%), mild (20 - 40%), moderate (40-60%), severe (60-80%), intolerable pain (>80%).	pain:5%	pain:0%	"There was also no difference in the investigator's pain estimation between the two groups at a 5% level (P= 0.693)." two-sample t-test.
	3. Parent reported Pain (VAS, 0-100%), after LA. Percentages were divided them into three categories: no pain (<20%), mild (20 - 40%), moderate (40-60%), severe (60-80%), intolerable pain (>80%).	not reported	not reported	"There was no significant difference in parent pain estimation between the two groups (P=0.640)." two-sample t-test.
Study	**Outcome**	**Intervention**	**Control**	**Result**
Versloot 2005	Pain-related behaviour (5-category scale of distress),15-s intervals, prior to and during delivery of LA, investigator.	Muscle tension		Anticipation phase: "no significant differences were found" First 15-s interval: "children in the Wand group showed less
		Anticipation: 48(n=67) First interval: 72 (n=67) Second interval: 73(n=67)	Anticipation: 62 (n=58) First interval: 91 (n=58) Second interval: 93 (n=42)	
		Cry/scream		
		Anticipation: 13(n=67) First interval: 33 (n=67)	Anticipation: 19(n=58) First interval: 50(n=58) Second interval: 45(n=42)	

	The occurrence of behaviours is summed and divided over the number of intervals to calculate the mean score of the pain related behaviours.	Second interval: 37(n=67)		body movement, muscle tension, and verbal protest." Second 15-s interval: "children injected using the Wand still showed less muscle tension and less verbal protest"
		verbal protest		
		Anticipation: 8(n=67) First interval: 12 (n=67) Second interval: 2 (n=67)	Anticipation: 10(n=58) First interval: 26 (n=58) Second interval: 12(n=42)	
		body movement		
		Anticipation: 12(n=67) First interval: 13 (n=67) Second interval: 18(n=67)	Anticipation: 24(n=58) First interval:35 (n=58) Second interval: 17(n=42)	
		resistance		
		Anticipation: 5(n=67) First interval: 8 (n=67) Second interval: 8 (n=67)	Anticipation: 9(n=58) First interval: 14(n=58) Second interval: 14(n=42)	
	Distress: (Modified Venham's clinical rating of anxiety and co-operative behaviour). 6 points, 1- 6; prior to and during delivery of LA; investigator	Anticipation (prior to LA)		"Less distress was displayed during the first two intervals of the injection phase when injected using the Wand than when injected in the traditional way although this difference did not reach significance" multivariate GLM, F (3,105) . 1.29, P . 0.283;
		Mean: 0.81 (CI 0.54–1.08, 95%) n=67	Mean: 1.12 (CI (0.78–1.46, 95%) n=42	
		First 15-s interval		
		Mean: 1.09 (CI 0.81–1.37, 95%) n=67	Mean: 1.48 (CI 1.13–1.83, 95%) n=42	
		Second 15-s interval		
		Mean: 1.09 (CI 0.82–1.37, 95%) n=67	Mean: 1.52 (CI 1.18–1.87, 95%) n=42	
	Self-reported pain (modified VAS), 11	Mean: 4.40 (3.22 sd)	Mean: 3.76 (3.57 sd)	no difference

	points (0-10); after LA; participants.			
Study	**Outcomes**	**Intervention**	**Control**	**Results**
Versloot 2008	Pain-related behaviour (5-category scale of distress),15-s intervals, prior to and during delivery of LA, investigator. The occurrence of behaviours is summed and divided over the number of intervals to calculate the mean score of the pain related behaviours.	First appointment		
		Mean: 1.03 (0.83 sd) n=66	Mean: 1.14 (1.27 sd) n=74	"There was no difference for (…) the mean number of pain related behaviours (…) between children injected with the Wand or the traditional injection". Mancova used.
		Second appointment		
		Mean: 0.89 (1.21 sd) n=55	Mean: 1.19 (1.20 sd) n=64	"there was no difference for (…) the mean number of pain related behaviours (…) for children injected with the Wand or the traditional injection", Mancova used
	Distress: (Modified Venham's clinical rating of anxiety and co-operative behaviour). 6 points, 1- 6; prior to and during delivery of	First appointment		
		Mean: 1.38 (0.94 sd) n=66	Mean: 1.48 (1.24 sd) n=74	"There was no difference for the mean Venham score, (…) between children injected with the Wand or the traditional injection". Mancova used.

	LA; investigator	Second appointment		
		Mean: 1.31 (1.21 sd) n=55	Mean: 1.50 (1.17 sd) n=64	Thus there was no difference for the mean Venham score, (…) for children injected with the Wand or the traditional injection." Mancova used.
	Self-reported pain (modified VAS), 11 points (0-10); after LA; participants.	First appointment		
		Mean: 3.26 (3.27 sd) n=66	Mean: 2.77 (3.00 sd) n=74	"There was no difference for the (…) self-reported pain score between children injected with the Wand or the traditional injection". Mancova used.
		Second appointment		
		Mean: 3.49 (3.40 sd) n=55	Mean: 3.77 (3.30 sd) n=64	"there was no difference for the mean (…) the self-reported pain score for children injected with the Wand or the traditional injection." Mancova used.

Comparison 4: The wand versus sleeper one (one study)

Study	**Outcome**	**Intervention 1: sleeper one**		**Intervention 2: the wand**		**Results**
Nieuwenhuizen 2013	1. Pain-related behaviour (modified Wong-Baker faces scale); 15s. Reported	Muscle tension	Mean: 0.41 (0.39	Muscle tension	Mean: 0.42 (0.38	p=0.765 (Mann–Whitney

	separately for each category: body movement, muscle tension, crying and screaming, verbal protest and bodily resistance The frequency of the behaviour was divided by the total number of intervals scored.		sd) n=52		sd) n=60	U test. P<0.01)
		Crying	Mean: 0.17 (0.31 sd) N=52	Crying	Mean: 0.25 (0.34 sd) N=60	p=0.220 (Mann–Whitney U test. P<0.01)
		Verbal protest	Mean: 0.07 (0.17 sd) N=52	Verbal protest	Mean: 0.07 (0.15 sd) N=60	p= 0.507 (Mann–Whitney U test. P<0.01)
		Body movement	Mean: 0.03 (0.06 sd) N=52	Body movement	Mean: 0.09 (0.18 sd) N=60	p= 0.165 (Mann–Whitney U test. P<0.01)
		Resistance	Mean: 0.01 (0.05 sd) N=52	Resistance	Mean: 0.07 (0.22 sd) N=60	p= 0.070 (Mann–Whitney U test. P<0.01)
	2. Distress (modified Venham scale, 0-5) highest score of appointment	Mean 0.96 (0.86 sd), n=52		Mean 1.42 (1.15 sd), n=60		p= 0.842 (Mann–Whitney U test. P<0.01)
	3. Self-reported pain: FPS-R, 0-10)	Mean 3.42 (4.16 sd), n=52		Mean 4.10 (3.97 sd), n=60		p= 0.265 (Mann–Whitney U test. P<0.01)

Table 14: Comparison 5: camouflage syringe versus conventional

Study	Outcome	Intervention	Control	Results
Ujaoney 2013	Pain (VPT; 9 point-scale, 0-8, self reported after LA)	point 1(crying): 0(n=50)	point 1(crying): 21(n=50)	p<0.0001 (Mann-Whitney)
		point 2 (smiling): 44 (n=50)	point 2 (smiling): 1(n=50)	p<0.0001 (Mann-Whitney)
		other points in scale not statistically significant. Overall scores not compared.		

Table 15: Comparison 6: counter-stimulation/distraction versus control

Study	Outcome	Intervention	Control	Results
Lee 2013	Distress: (SEM scale; 3 categories), intra-operatively, investigator	comfort: 76 mild pain: 3 moderate pain: 1 severe pain: 0	comfort: 32 mild pain: 12 moderate pain: 1 severe pain: 9	"A significant difference existed regarding pain response between the alternative and conventional groups based on SEM ratings ($P < 0.000$)."(Chi-square)
Study	**Outcome**	**Intervention-Manual stimulation**	**Control**	**Result**
Tung 2018	Pain perception(pain reporting) after the injection using Wong Baker FACES Pain Rating Scale 0 to 10 where worst pain	2.76±2.5 n=50	3.56±2.9 n=50	The mean pain score was lowest for the manual stimulation (2.76±2.5) compare to no stimulation group(3.56±2.9).
	Anxiety changes using pulse rate at four different times (during LA) (baseline, during application of topical anaesthetic, during the injection; and immediately after the	Change from baseline (95% CI) **During the injection** **4.3 (1.6, 7.0)** Post-injection 8.2 (5.2, 11.2)	Change from baseline (95% CI) **During the injection** **2.3 (-0.4, 5.0)** Post-injection 5.0 (2.0, 8.0)	As expected, the injection time point showed an increased heart rate from baseline in all groups. At the post injection time point, there was also an increase in heart rate for all groups. The greatest change in pulse rate from baseline to post-injection was

				found in the manual stimulation group (8.2; IQR=5.2 to 11.2), followed by the control (5.0; IQR = two to eight)
Study	**Outcome**	**Intervention**	**Control**	**Results**
Kamath 2013	Pain (modified toddler-preschooler post operative pain scale)	2.46 (1.752 sd)n=28	5.64 (2.328 sd) n=28	"The use of WITAUL (Writing In The Air Using Leg) was found to be statistically significant compared to the control method with a p value of 0.0001"
Study	**Outcome**	**Intervention/distraction second appointment**	**Control second appointment**	**Results**
Sridhar 2019	Pain- related behaviour recorded at the time of injection using Frankl's behaviour rating Scale during LA (1 = definitely negative, 2 = slightly negative, 3 = slightly positive, 4 = definitely positive)			The authors reported that Behaviour, as measured by the Frankl scale was similar in both the groups. The frequency of children exhibiting negative (n = 6; 18.2%), positive (n = 24; 72.7%), and definitely positive behaviour (n = 3; 9.1%) was the same in both groups ($\chi 2$ = 0.00, P = 1).

				The presented result not clear and decided to exclude this outcome from the review
	Pain experience using the Faces Legs Activity Cry and Consolability (FLACC) scale. 0 to 10 where is 10 worst pain	Dichotomous Relaxed: n 12 Mild discomfort: n 20 Moderate discomfort: N 1 Sever discomfort: n 0	Relaxed: n 0 Mild discomfort: n 14 Moderate discomfort: N 19 Sever discomfort: n 0	The results of the FLACC scale (observational measure) for pain using the chi-square test shows that children belonging to the relaxation exercise group perceived lesser pain with a statistically significant difference between the two groups according to the authors.
	Pain perception (reported) using Wong-Baker FACES pain scale immediately afterLA 0 to 6 where 6 worst pain The WBFPRS is a self-reported scale of six faces, that range from a smiling ‘no hurt’ face on the left to a crying ‘hurts	1.51 ± 0.67	2.45 ± 0.56	Pain perceived as measured by the WBFPRS (self-reported measure) using the Mann-Whitney U test showed a statistically significant difference between the two groups with children in the relaxation exercise group reporting lesser pain perceived as compared to the control group p= <0.001.

	worst face' on the right.			
	Dental anxiety measured using the Facial Image Scale (pre-procedure-before the treatment) (five faces ranging from very happy to very unhappy) 0-5 where 5 very unhappy	1.57 ± 0.56	1.84± 0.61	Intergroup comparison using Mann-Whitney U test also showed that the groups were comparable for dental anxiety with no statistically significant difference in anxiety between the groups at both the first and second appointments P= 0.073 Excluded from the review as this scale were used before the start of treatment n
	Anxiety changes using pulse rate at three different times(during LA)	Pulse rate 5 min before injection: 93.30 ± 8.52 **Pulse rate during injection: 96.21 ± 8.76** Pulse rate 5 min after injection: 92.52 ± 8.03	Pulse rate 5 min before injection: 96.00 ± 10.27 **Pulse rate during injection: 97.33 ± 9.28** Pulse rate 5 min after injection: 94.76 ± 8.73	Pulse rate measured using the repeated measures ANOVA at three different time intervals (5 minutes before, during, and 5 minutes after injection) between the two groups showed comparable values with no statistically significant difference. F=1.009, P=0.319

Study	Outcome	Group 1: Passive distraction	Group 2: Active distraction	Group 3: Passive-active distraction	Results
Abdelmoniem 2016	1. Pain perception during administration of local anaesthesia: assessed by the Wong Baker FACES Pain Rating Scale	Box plot given, no numeric data available			
	2. Observed pain: assessed by sounds, Eyes, and Motor (SEM) scale. It is divided into two categories of comfort and discomfort. The discomfort response is further divided into three sub scales: mild pain, moderate pain and severe pain.	Comfort: 14 patients (46.7%) Mild pain: 10 (33.3%) Moderate pain: 4 (13.3%) Severe pain: 2 (6.7%)	Comfort: 18 (60%) Mild pain: 5 (16.7%) Moderate pain: 7 (23.3%) Severe pain: 0	Comfort: 15 (50%) Mild pain: 10 (33.3%) Moderate pain: 4 (13.3%) Severe pain: 1 (3.3%)	p=0.73
Study	**Outcome**	**Intervention 1: counter-stimulation (groups C+SA)**	**Control: conventional LA (group SA)**		**Results**
Amiabadi 2008	Distress: (SEM scale; 0-4 for each of 4 categories), intra-	sound:1.67 eye: 1.67 movement: 1.73 sum: 5.07 (n=26)	sound:2.75 eye: 2.67 movement: 2.83 sum: 8.25 (n=26)		"difference between group SA and group C+SA was statistically significant ($p<0.05$); group

	operatively, investigator			CD+SA surpassed group SA ($p<0.05$) Pain reaction on C+SA significantly more than group CD+SA ($p<0.05$)

Table 16: Comparison 7: Electrical counter-stimulation device(DentalVibe) versus conventional LA

Study	Outcome	Intervention	Control	Result
Tung 2018	Pain experience(pain reporting) after the injection using Wong Baker FACES Pain Rating Scale 0 to 10 where worst pain	2.22±2.2 n=50	3.56±2.9 n=50	The authors stated" We found a statistically significant difference in the FACES score between the control group and the DentalVibe® group, with those in the control group reporting a half-point reduction in the FACES pain score (P<.001).
	Anxiety changes using pulse rate at four different times (during LA) (baseline, during application of topical anaesthetic, during the injection; and immediately after the	Change from baseline (95% CI) **During the injection 2.9 (0.3, 5.6)** Post-injection 4.1 (1.1, 7.1)	Change from baseline (95% CI) **During the injection 2.3 (-0.4, 5.0)** Post-injection 5.0 (2.0, 8.0)	The authors stated that the least change was with the DentalVibegroup (4.1; IQR = 1.1 to 7.1) from the baseline compare to the other group.

Table 17: Comparison 8: Counter-stimulation versus counter-stimulation and distraction, versus control

Study	Outcome	Intervention 1: counter-stimulation	Intervention 2: distraction and counter-stimulation	Control: conventional LA (group SA)	Results

		(groups C+SA)	**(group CD+SA)**		
Amiabadi 2008	Distress: (SEM scale; 0-4 for each of 4 categories), intra-operatively, investigator	sound:1.67 eye: 1.67 movement: 1.73 sum: 5.07 (n=26)	sound:1.26 eye: 1.03 movement: 1.12 sum: 3.41 (n=26)	sound:2.75 eye: 2.67 movement: 2.83 sum: 8.25 (n=26)	"difference between group SA and group C+SA was statistically significant ($p<0.05$); group CD+SA surpassed group SA ($p<0.05$) Pain reaction on C+SA significantly more than group CD+SA ($p<0.05$)

Table 18: Comparison 9: hypnosis versus conventional treatment

Study	**Outcome**	**Intervention**	**Control**	**Results**
Huet 2015	Anxiety (mYPAS4; 22 categories, 0-100), self-reported	median: 23	median: 50	p=0.021 (Mann-Whitney test)
	Pain (mOPS; 5 categories, 0-10; investigator reported)	mean: 1.07 (1.05 sd)	mean: 2.86 (2.16 sd)	p<0.05 (Mann-Whitney test)
	Pain (VAS; 0-10; self reported after la)	VAS of zero: 4 (n=14)	VAS of zero: 2 (n=15)	chi square:10.08; df=1; p=0.001
		VAS > or = three: 2 (n=14)	VAS > or = three: 9 (n=15)	chi square:6.43; df=1; p=0.0112
Study	**Outcome**	**Intervention**	**Control**	**Results**
Carrasco 2017	Pain perception were assessed with the FLACC scale((Face, Legs, Activity, Cry, Consolability) during LA	Mean 2.65	Mean 2.10	The authors reported that No statistically significant differences were found with the FLACC Scale P= 0.5
	Heart rate before and during LA	Heart rate before LA (base line) 92.31	Heart rate before LA (base line) 94.16	The authors reported that

		Heart rate during LA 93.57 Heart rate difference between the before and during −1.254	Heart rate during LA 99.3 Heart rate difference between the before and during −5.767	there was a difference of 5 beats per minute between the basal point and the point of administering anaesthesia in the control group, while no difference was detected for the hypnosis group (P= 0.05)
	skin conductance before and during LA	Use of skin conductance as an outcome measure is not clear yet and not well justified, as there are few studies to support it use in dentistry. Decide to exclude this outcome measure in this review.		
Study	**Outcome**	**Intervention**	**Control**	**Results**
Oberoi 2016	Physical and verbal resistance: resistance to delivery of LA	Percentage of patients that showed no resistance: 68.1%	Percentage of patients that showed no resistance: 31.9%	Statistically significantly more patients showed resistance in the control group ($p<0.05$) authors don't specify which tests were used for each comparison. “Descriptive statistics, a chi-squared test, and a t test were used to establish the relationship between the groups”
	Change in oxygenation level: from baseline until LA delivery.	Before LA Mean: 97.90 (SD=0.72) After LA Mean: 97.81 (SD=0.61)	Before LA Mean: 97.75 (SD=0.69) After LA Mean: 97.85 (SD=0.46)	No statistically significant difference between groups p=0.095
	Pulse rate: measured at baseline, at tissue penetration and on administration of LA	Before LA Mean: 107.92 (SD=4.65) After LA Mean: 93.17 (SD=4.65)	Before LA Mean: 103.93 (SD=4.46) After LA Mean: 108.23 (SD=4.79)	Statistical significantly reduced pulse rate in treatment group (group 1 p=0.000

Table 19: Comparison 10: video modelling for LA versus video modelling for oral hygiene

Study	Outcome	Intervention	Control	Results
Al-Namankany	Visual Analogue Scale	in the waiting room mean: 7.05 (19.64 sd)	in the waiting room mean: 15.97(22.17 sd)	difference in means= -8.9 (95% CI -20.17 to 2.34) p= 0.12 difference in means: -8.9
		entering the dental clinic mean: 22.88, (26.5 sd)	entering the dental clinic mean: Mean 33.25 (25.21 sd)	difference in means = -10.37 (95% CI -24.23 to 3.48) p= 0.14
		sitting the dental chair mean: 13.39 (15.45 sd)	sitting the dental chair mean: Mean 31.6 (24.73sd)	difference in mean = -18.21 (95% CI -29.35 to -7.06) p=0.002
		local anaesthetic Mean: 23.12 (26.70 sd)	local anaesthetic Mean 86.55(21.43 sd)	difference in means = -63.42 (95% CI -76.71 to -50.13) p <0.001

Table 20: Comparison 11: video modelling acclimatisation versus acclimatisation in clinic

Study	Outcome	Intervention	Control	Results
Paryab	Heart rate	prior to LA: 102.80 (12.91 sd)	prior to LA: 98.89 (10.16 sd)	p=0.31 (t test)
		Following LA:113.90 (14.70 sd)	Following LA:111.17 (11.93 sd)	p=0.53 (t test)

1 Audiovisual distraction versus music distraction versus control

Outcome or Subgroup	Studies	Participants	Statistical Method	Effect Estimate
1.1 Pain-related behaviour - dichotomous (participant with negative behaviour versus participant with positive behaviour)	1		Risk Ratio (M-H, Fixed, 95% CI)	Subtotals only
1.1.1 Audiovisual distraction with 3D video glasses versus control group during LA	1	60	Risk Ratio (M-H, Fixed, 95% CI)	0.13 [0.03, 0.50]
1.1.2 Music distraction group versus control during LA	1	60	Risk Ratio (M-H, Fixed, 95% CI)	0.31 [0.13, 0.74]
1.1.3 Audiovisual distraction with 3D video glasses versus music group during LA	1	60	Risk Ratio (M-H, Fixed, 95% CI)	0.40 [0.08, 1.90]
1.2 Pain-related behaviour (FLACC scale 0–10, higher score indicates worst behaviour)	1		Mean Difference (IV, Fixed, 95% CI)	Subtotals only
1.2.1 VR box versus control LA	1	67	Mean Difference (IV, Fixed, 95% CI)	-0.03 [-1.03, 0.96]
1.2.2 Tablet versus control LA	1	68	Mean Difference (IV, Fixed, 95% CI)	0.67 [-0.41, 1.76]
1.2.3 VR box versus tablet	1	67	Mean Difference (IV, Fixed, 95% CI)	-0.71 [-1.84, 0.43]
1.3 Pain experience (Wong-Baker Faces score 0-5, higher score indicates worst pain)	1		Mean Difference (IV, Fixed, 95% CI)	Subtotals only
1.3.1 VR box versus control LA	1	67	Mean Difference (IV, Fixed, 95% CI)	0.04 [-0.41, 0.48]
1.3.2 Tablet versus control LA	1	68	Mean Difference (IV, Fixed, 95% CI)	0.22 [-0.28, 0.73]
1.3.3 VR box versus tablet	1	67	Mean Difference (IV, Fixed, 95% CI)	-0.19 [-0.73, 0.35]
1.4 Anxiety after LA (any distraction vs control) (Modified Child Dental Anxiety Scale score form	1		Mean Difference (IV, Fixed, 95% CI)	Subtotals only

5-30, higher scores indicate higher anxiety)				
1.4.1 Audiovisual distraction with 3D video glasses versus control group after LA	1	60	Mean Difference (IV, Fixed, 95% CI)	-12.60 [-15.33, -9.87]
1.4.2 Music distraction group versus control after LA	1	60	Mean Difference (IV, Fixed, 95% CI)	-6.80 [-9.82, -3.78]
1.5 Anxiety between distraction techniques after LA (Modified Child Dental Anxiety Scale score form 5-30, higher scores indicate higher anxiety)	1	60	Mean Difference (IV, Fixed, 95% CI)	-5.80 [-7.61, -3.99]
1.6 Pulse rate during LA (any distractions versus control)	1		Mean Difference (IV, Fixed, 95% CI)	Subtotals only
1.6.1 Music distraction group versus control during LA	1	60	Mean Difference (IV, Fixed, 95% CI)	-14.40 [-19.20, -9.60]
1.6.2 Audiovisual distraction versus control group during LA	1	60	Mean Difference (IV, Fixed, 95% CI)	-9.60 [-14.62, -4.58]
1.6.3 Pulse rate difference between 2 distraction techniques during LA	1	60	Mean Difference (IV, Fixed, 95% CI)	-4.80 [-6.87, -2.73]
1.7 Pulse rate before and after LA	1		Mean Difference (IV, Fixed, 95% CI)	Subtotals only
1.7.1 VR box versus control LA	1	67	Mean Difference (IV, Fixed, 95% CI)	2.88 [-1.78, 7.53]
1.7.2 Tablet versus control LA	1	68	Mean Difference (IV, Fixed, 95% CI)	6.26 [2.04, 10.47]
1.7.3 VR box versus tablet	1	67	Mean Difference (IV, Fixed, 95% CI)	-3.38 [-8.42, 1.66]

2 The wand versus traditional LA

Outcome or Subgroup	Studies	Participants	Statistical Method	Effect Estimate
2.1 Any disruptive behaviour (body movements, crying, restraint and stoppage of	3		Mean Difference (IV, Random, 95% CI)	No totals

treatment) by the child during LA				
2.2 Pain perception/pain experience during the intervention	4		Mean Difference (IV, Random, 95% CI)	No totals
2.2.1 Any site of injection	4		Mean Difference (IV, Random, 95% CI)	No totals
2.2.2 Palatal site injection	1		Mean Difference (IV, Random, 95% CI)	No totals
2.3 Pain perception during the intervention (dichotomous)	2		Risk Ratio (M-H, Fixed, 95% CI)	Subtotals only
2.3.1 No pain versus any pain	2	68	Risk Ratio (M-H, Fixed, 95% CI)	1.15 [0.83, 1.59]
2.3.2 No pain and mild pain versus any pain	2	68	Risk Ratio (M-H, Fixed, 95% CI)	1.12 [0.85, 1.47]
2.4 Anxiety changes during the intervention	4		Mean Difference (IV, Random, 95% CI)	No totals
2.4.1 Any site of injections	4		Mean Difference (IV, Random, 95% CI)	No totals
2.4.2 Palatal injection	1		Mean Difference (IV, Random, 95% CI)	No totals

3 The wand versus Sleeper One

Outcome or Subgroup	Studies	Participants	Statistical Method	Effect Estimate
3.1 Any disruptive behaviour (body movements either present or absent during each 15-second interval of the injection phase)	1	112	Mean Difference (IV, Fixed, 99% CI)	0.06 [0.01, 0.11]
3.2 Pain experience (Faces Pain Scale-Revised (FPS-R) 0–10 with higher score indicates worst pain)	1	112	Mean Difference (IV, Fixed, 99% CI)	0.68 [-1.31, 2.67]
3.3 Anxiety changes (modified Venham's, 0-6 scale, higher score indicates higher anxiety)	1	112	Mean Difference (IV, Fixed, 99% CI)	0.46 [-0.03, 0.95]

4 Camouflage syringe versus conventional syringe

Outcome or Subgroup	Studies	Participants	Statistical Method	Effect Estimate

4.1 Pain-related behaviour	1		Risk Ratio (M-H, Fixed, 95% CI)	Subtotals only
4.1.1 Children who cried	1	100	Risk Ratio (M-H, Fixed, 95% CI)	0.02 [0.00, 0.37]
4.1.2 Children who did not smile	1	100	Risk Ratio (M-H, Fixed, 95% CI)	0.12 [0.06, 0.26]
4.2 Overall anxiety and behavioural changes (Venham's clinical rating scale, from 0 to 5 with 5 being the worst)	1		Mean Difference (IV, Fixed, 95% CI)	Subtotals only

5 Counter-stimulation or distraction versus conventional treatment

Outcome or Subgroup	Studies	Participants	Statistical Method	Effect Estimate
5.1 Pain experience (dichotomous)	2		Risk Ratio (M-H, Fixed, 95% CI)	No totals
5.1.1 Any pain versus no pain (comfort versus discomfort)	2		Risk Ratio (M-H, Fixed, 95% CI)	No totals
5.2 Pain perception	3		Mean Difference (IV, Fixed, 95% CI)	No totals
5.2.1 Children aged 6-14 years	3		Mean Difference (IV, Fixed, 95% CI)	No totals
5.2.2 Children younger than 5 years old	1		Mean Difference (IV, Fixed, 95% CI)	No totals
5.3 Anxiety changes (pulse rates)	2		Mean Difference (IV, Fixed, 95% CI)	No totals
5.3.1 Changes from baseline to during injection LA	1		Mean Difference (IV, Fixed, 95% CI)	No totals
5.3.2 Pulse rate during LA	1		Mean Difference (IV, Fixed, 95% CI)	No totals

6 Electrical counter-stimulation (DentalVibe) versus no stimulation

Outcome or Subgroup	Studies	Participants	Statistical Method	Effect Estimate
6.1 Pain experience (self-reported pain)	1	100	Mean Difference (IV, Fixed, 95% CI)	-1.34 [-2.35, -0.33]
6.2 Anxiety changes (pulse rates changes from baseline to during injection recorded pulse rates)	1	100	Mean Difference (IV, Fixed, 95% CI)	0.60 [-3.06, 4.26]

7 Hypnosis versus conventional treatment

Outcome or Subgroup	Studies	Participants	Statistical Method	Effect Estimate
7.1 Pain perception	2		Mean Difference (IV, Fixed, 95% CI)	Subtotals only
7.2 Pain experience (dichotomous - VAS, 0-10, higher score indicates worst pain)	1		Risk Ratio (M-H, Fixed, 95% CI)	Subtotals only
7.2.1 Pain reporting (VAS >3)	1	29	Risk Ratio (M-H, Fixed, 95% CI)	0.24 [0.06, 0.92]
7.3 Anxiety (number of participants that exhibit physical or verbal resistance to LA - dichotomous)	1	200	Risk Ratio (M-H, Fixed, 95% CI)	0.47 [0.34, 0.65]
7.4 Physiological assessment - pulse rates	2		Mean Difference (IV, Fixed, 95% CI)	No totals
7.4.1 Pulse rate before LA	1		Mean Difference (IV, Fixed, 95% CI)	No totals
7.4.2 Pulse rate during LA	1		Mean Difference (IV, Fixed, 95% CI)	No totals
7.4.3 Pulse rate after LA	1		Mean Difference (IV, Fixed, 95% CI)	No totals

8 Video modelling acclimatisation for LA versus oral hygiene video

Outcome or Subgroup	Studies	Participants	Statistical Method	Effect Estimate
8.1 Anxiety	1	66	Mean Difference (IV, Random, 95% CI)	-37.16 [-50.94, -23.38]

9 Video modelling acclimatisation versus acclimatisation in clinic

Outcome or Subgroup	Studies	Participants	Statistical Method	Effect Estimate
9.1 Co-operative behaviour level using Frankl 4-point index	1		Mean Difference (IV, Fixed, 95% CI)	No totals
9.2 Anxiety changes (6-point index, higher score indicates worst anxiety)	1		Mean Difference (IV, Fixed, 95% CI)	Subtotals only

APPENDIX 4: Topic guide

Structured questions for parent Interviews

These questions are guides only and will serve as general guideline interview discussion sessions with parent

introduction

Can you please tell me about yourself?

i. education level, material status?
ii. do you have any other children in the family with additional needs?
iii. tell me about your child needs and health condition?
iv. who's is usually involve with your child dental need?

Section A. Oral health condition

1. What you're understanding of oral health?

   Clues

   i. Is it important to have a health mouth for you and your child?
   ii. Do you think oral health is relevant to your child general health?
   iii. What are your responsibilities and roles with your child's oral health?

2. please tell me your experience going to the dentist

   Clues:

   i. teeth primary or permanent
   ii. gum
   iii. infection
   iv. any concerns at the moment

3. Does your child's oral health condition affect his daily life? And if yes how?
4. Are there any barriers or challenges that make it harder for your child to keep a good oral health (brushing..)?
5. Where do you usually go if you are seeking a dental treatment for your child (Specialist or general dentist)? Is it hard and why?

Section B. Going to the dentist

1. Please tell me about your experience going to the dentist with your child?

    Clues:

    i. what happened
    ii. when and how long (time)
    iii. what treatment was done
    iv. good or bad experience and if so did it affect your child
    v. any issues or complaints

2. Do you reach out to dentist only if your child under pain or not? Can you tell me more? And what are the reasons of taking and no taking your child to the dentist?

    Clues:

    i. time, cost, need and any other reasons

Section C. Treatment provided

1. What is your opinion about the dental treatment that your child receives?
    a. Clues:
        i. Limited

ii. Time consuming

iii. Costly

iv. Any other concerns or issues

2. What would say about the dentist management of your child dental needs before/during and after appointment?

    i. Are satisfy with the current treatment provided at the dental office? Could anything have been done differently/ better?
    ii. Any other point you want to raise

Section D. Additional care/dentist

1. What are your views on your child dentist?

    i. skill/ management and communication
    ii. knowledge of your child condition and needs
    iii. attitudes towards your child oral health needs and yourself
    iv. any other point you want to add

2. Does your child receive any additional attentions or measurements at the dentist office such as and not only to?

    i. Receive treatment in a special care unit/hospital setting or primary care unit when seeking a treatment. Why?

    ii. Placing fluoride annually/6months or pit and fissure sealant (placing protective layer on the tooth, protect the tooth with anti-decay agents, cover the tooth with some special way)

    iii. Advised of using a specific tooth paste/mouth rinse/tooth brush manual/electrical

    iv. Receive a regular check-up or cleaning teeth at the dentist (scaling)

    v. If yes, and not mentioned above, can you please tell me about it?

vi. If yes, is it affective or not and why?

vii. Any other point you want to add

3. Does your child dentist offer you support such as?

    i. provide access to information to assist your caring role, enough, limited
    ii. monitor the oral health condition of your child and offer help
    iii. any encouragement from the dentist to help out with maintaining a good oral health (brushing, regular check-up)
    iv. do you think it's important or not and way?

3. Have you been asked to be involve in your child's treatment or decision in making a treatment by the dentist?

    If not:

    i. Do you think it's important or not? Why?

4. What does your dentist do well to support children dental treatment?

5. What could your dentist do better or different to support your child in dental office?

Closing the interview

Is there anything else which seems to you important and that you would like to talk about? any comment?

Thanks for your time and contribution

I highly appreciate your contribution for this study and as I already mentioned everything will be very confidential and anonymous. I would also be very happy if you agree to contact in future regarding any clarifications about our interview topics.

APPENDIX 5: Interview transcript

Questions	Response	
Can you please tell me about yourself?	Ahhh ……I work in private sector….I'm 47 years old….I have a bachelor degree in science…my son is 7 years old…he was diagnosed with autism when he was three years old…we noticed when he was young,,,because he didn't speak well and also ….communication with us is poor…couldn't talk… His mother… she helps with the brushing…He even sometimes sleeps without brushing his teeth….Honestly speaking, we are not doing a good job with the brushing…..He sometimes throws up when we brush his teeth,,,,he doesn't like the taste of the toothpaste…and sometimes we brush without toothpaste…	Participant profile Resistance to brush
What you're understanding of oral health? Do you think it's important? Is it relevant to your child general health…?	Ahh…yeah..I think so…its important. I always try to go to the dentist more often for check-ups….of course we are paying attention for oral health and his teeth…we try to make sure his teeth are clean…look nice…every time we try to go to monitor as much as we can….	Importance of oral health
Does your child's oral health condition affect his daily life? ..?	No..no.. I mean I noticed that he had some cavity in his teeth when I help him with the brushing…because sometimes he doesn't clean them well…I need to be around her.	
please tell me your experience going to the dentist…	Ahh….at the beginning it was really hard…I mean…when he was younger.. his baby teeth had many issues…we tried to go many times just so that the dentist can see him…but we couldn't …When he got a bit older…it became easier for us…with a bit of encouraging and support from us… we were able to get some of his teeth fixed…the first time the dentist did not do a good job…he was bad with my son, but we went to other dentist. Actually he was a recent graduate…he was a really good…he was handling my son well…my son was very responsive with the treatment ..all it was because of his communication…	
Are there any barriers or challenges that make it harder for your child to keep a good oral health (brushing..),..?	Ahhh…. It's really hard for my son to brush his teeth by himself…and sometimes I fear that my son will not be able to be treated unless it's going to be under general anaesthesia …for only one tooth….. Sometimes it's hard for him to tell you where he is having the pain…this is the problem…with communication…we just hope for the better..	The use of GA

Where do you usually go if you are seeking a dental care for your child .. Is it hard and why?	Ahh…..to be honest…sometimes we go to general dentist and sometimes we try to go to specialists…..It depends…but most time we go to the private clinic….because it doesn't take a lot of time and also because they treat us in a good way…	Waiting time
Do you reach out to dentist only if your child under pain or not? Can you tell me more….? what are the reasons ..t?	Yeah…yeah..I mean if he complains, we try to go….from time to time…going to the dentist is hard for him ….. I tell him to brush his teeth so that he doesn't have to go. I mean it's hard when he has filling or something…because he moves a lot, and I have to be holding him and he does not like that at all.	Routine visits
What would say about your dentist? management of your child ? before/during and after appointment…?	Ahhh….it depends on the dentist, but after treatment there is no communication.	
Does your child dentist offer you support such as? Information…engorgement...	Ahh… I only remember one dentist who showed us how to brush…only one dentist…	Medical support and advice
Does your child receive any additional attentions or measurements at the dentist office such as and not only to?	No…no…. unfortunately no, I have heard of it before from one of my friends….and I even asked some private dentists, but they said they don't have it…I mean the fluoride…one dentist told me to buy it and bring it to the clinic but I didn't do it… I'm really eager to do it…I hope it's not too late to do…I remember one clinic had it but it was too expensive… I thought it was overpriced…. Nobody had asked to us to use…like specific tooth baste or tooth brush…no..	Additional measurements Medical support and advice

Have you been asked to be involved in your child's treatment or decision in making a treatment by the dentist?	Ahhh…. Most of them tell me what they are going to do,,,, I mean most of the dentist	
What does your dentist do well to support children dental treatment?	Ahh…I mean treating my child teeth and sitting with him so he doesn't get afraid from the sound of the tools in the clinic…such as the needle ..…this is important so the child doesn't focus on bad things around him…this is important for dentists to focus on especially with these children.	Behaviour issue
What could your dentist do better or different to support your child in dental office?	Ahhh…I mean some of the treatment are not available in some clinics…I mean for example the laughing gas….it is not available…also some clinics don't have paediatric dentists …I mean they treat all…one minute he/she treats adults and after that 40 years old man…this something I noticed…I mean I wish there are more clinics just for children…and it should be just for these children.	Ideal practice

APPENDIX 6: Ethical Approval

Research Governance, Ethics and Integrity

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The University of Manchester

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Manchester

M13 9PL

Tel: 0161 275 2206/2674

Email: research.ethics@manchester.ac.uk

Ref: 2020-8323-13621

13/03/2020

Dear Mr Hamdan Alamri, Dr Tanya Walsh, Prof Anne-Marie Glenny

Study Title: Oral care for children with special healthcare needs in Saudi Arabia

University Research Ethics Committee 2

I write to thank you for submitting the final version of your documents for your project to the Committee on 11/03/2020 11:20 . I am pleased to confirm a favourable ethical opinion for the above research on the basis described in the application form and supporting documentation as submitted and approved by the Committee.

Please see below for a table of the title, version numbers and dates of all the final approved documents for your project:

Document Type	File Name	Date	Version
Default	Interview topic guide	09/12/2019	1
Advertisement	Invitation letter to the school director v01	12/12/2019	01
Lone Worker Policy/Procedure	Personalised Lone working Plan	03/01/2020	01
Additional docs	Verification of translated documents	03/01/2020	01
Additional docs	Letter to the school head-teacher(Arabic tranlation)	07/01/2020	01
Additional docs	Structured questions for parent Interviews(Arabic translation)	07/01/2020	01
Advertisement	email to the parent and carer v02	18/02/2020	v02
Advertisement	Letter to the parent and carer v02	18/02/2020	v02
Additional docs	email to the parent and carer(Arabic translation)	18/02/2020	v02
Additional docs	Recruitment for research study(Arabic version)	18/02/2020	v02
Distress Protocol/Debrief Sheet	Distress protocol or debrief sheet	18/02/2020	v02
Additional docs	Letter from the ethics committee	10/03/2020	v02
Consent Form	new consent form v03	10/03/2020	v03
Participant Information Sheet	Participant Information Sheet (PIS) v03-3	10/03/2020	v03
Additional docs	Consent form(s-Arabic version)	10/03/2020	v03
Additional docs	Participant information sheet(Arabic version)	10/03/2020	v03
Data Management Plan	An_investigation_into_parent_perception_and_experience_of_delivered_oral_care_for_children_with_spec-4	10/03/2020	v03
Additional docs	Response letter 2 for Oral care for children with special healthcare needs in Saudi Arabia	10/03/2020	v02

This approval is effective for a period of five years however please note that it is only valid for the specifications of the research project as outlined in the approved documentation set. If the project continues beyond the 5 year period or if you wish to propose any changes to the methodology or any other specifics within the project, an application to seek an amendment must be submitted for review. Failure to do so could invalidate the insurance and constitute research misconduct.

You are reminded that, in accordance with University policy, any data carrying personal identifiers must be encrypted when not held on a secure university computer or kept securely as a hard copy in a location which is accessible only to those involved with the research.

Reporting Requirements:

You are required to report to us the following:

1. Amendments: Guidance on what constitutes an amendment
2. Amendments: How to submit an amendment in the ERM system
3. Ethics Breaches and adverse events
4. Data breaches
5. Notification of progress/end of the study

Feedback

It is our aim to provide a timely and efficient service that ensures transparent, professional and proportionate ethical review of research with consistent outcomes, which is supported by clear, accessible guidance and training for applicants and committees. In order to assist us with our aim, we would be grateful if you would give your view of the service that you have received from us by completing a **UREC Feedback Form**. Instructions for completing this can be found in your approval email.

We wish you every success with the research.

Yours sincerely,

Mrs Genevieve Pridham

Secretary to University Research Ethics Committee 2

APPENDIX 7: The appraisal of evidence base – search strategy

MEDLINE Ovid search strategy

1. Disabilities.mp.
2. special healthcare need.mp.
3. special health need.mp.
4. exp Disabled Children/
5. exp Intellectual Disability/
6. exp Developmental Disabilities/
7. medical compromised.mp.
8. medical ill.mp.
9. limitation.mp.
10. ((deficien$ or low$) adj3 (cognition or "cognitive function$" or reason$ or intelligence)).ti,ab.
11. ("special needs" or (special adj3 child$) or retard$ or "slow learner$").ti,ab.
12. or/1-11
13. exp Child/
14. children.mp.
15. exp Child, Preschool/
16. exp Adolescent/
17. exp Young Adult/
18. or/13-17
19. 12 and 18
20. Dental care /
21. exp Dental Care/
22. exp Oral hygiene/
23. Oral health/
24. ((oral or dental) adj2 (hygiene or care)).ti,ab.
25. (oral adj6 care$).ti,ab.
26. ((oral or mouth) adj5 care).ti,ab.
27. (toothbrush$ or tooth-brush$ or floss$ or "chewing stick$" or "wood stick$" or toothpick$).ti,ab.
28. Health education, dental/

29. ((health$ adj3 promot$) and (dental or teeth or mouth or periodont$ or gingival$ or "oral health")).ti,ab.
30. Management.mp.
31. Treatment.mp.
32. or/20-31
33. 19 and 32